

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

BOEHRINGER INGELHEIM  
PHARMACEUTICALS INC., BOEHRINGER  
INGELHEIM INTERNATIONAL GMBH,  
BOEHRINGER INGELHEIM CORPORATION,  
AND BOEHRINGER INGELHEIM PHARMA  
GMBH & CO. KG,

Plaintiffs,

- against -

HEC PHARM CO., LTD., HEC PHARM USA,  
MYLAN PHARMACEUTICALS INC., MYLAN  
INC., MYLAN LABORATORIES LIMITED,  
ACCORD HEALTHCARE, INC., AUROBINDO  
PHARMA LIMITED, AUROBINDO PHARMA  
USA, INC., DR. REDDY'S LABORATORIES,  
LTD., DR. REDDY'S LABORATORIES, INC.,  
ZYDUS PHARMACEUTICALS USA, INC.,  
CADILA HEALTHCARE LTD., MSN  
LABORATORIES PRIVATE LIMITED, MSN  
PHARMACEUTICALS, INC., PRINSTON  
PHARMACEUTICAL INC., INVAGEN  
PHARMACEUTICALS INC., SUN  
PHARMACEUTICAL INDUSTRIES LTD.,  
SUN PHARMA GLOBAL FZE, SUN  
PHARMACEUTICAL INDUSTRIES, INC.,  
TEVA PHARMACEUTICALS USA, INC.,

Defendants.

Case No. 3:15-cv-05982-PGS-TJB



**PLAINTIFFS' OPPOSITION TO HEC'S  
MOTION FOR MISCELLANEOUS RELIEF**

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## INTRODUCTION

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The Court should deny HEC's motion.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

HEC's argument is wholly divorced not only from logic [REDACTED]

[REDACTED]

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<sup>1</sup> "HEC" refers to HEC Pharm Co., Ltd., and HEC Pharm USA Inc.

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] HEC's position "sounds absurd, because it is." *Sekhar v. United States*, 570

U.S. 729, 738 (2013). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



**FACTUAL BACKGROUND**

**I. After Years of Research, Boehringer Invented and Patented The Novel Compound Linagliptin And Related Methods Of Administration and Treatment**

Type-2 diabetes mellitus (“T2DM”) is a metabolic disorder characterized by abnormally high blood sugar levels. D.I. 618 at 7. In a healthy person, if blood sugar rises above a certain level, the body secretes insulin, which helps lower blood sugar levels. *Id.* In T2DM patients, this mechanism does not function properly, and blood sugar levels remain chronically high. *Id.* T2DM is a progressive disease that leads to complications such as an increased risk of stroke, blindness, limb amputation, and renal impairment. *Id.* T2DM is among the leading causes of kidney failure and the most common cause of end-stage renal disease in the United States. In addition, since many diabetes medications are eliminated mostly through the kidneys, diabetes patients with renal impairment are required to visit their doctors frequently to monitor their renal function and adjust their medication dose. *Id.* at 7, 8.

During the 1990s, Boehringer spent years trying to develop improved T2DM drugs to address these issues. *Id.* at 10. During this effort, Boehringer developed a proprietary test assay, screened more than a half million molecules for activity, and synthesized and tested more than 1,500 novel compounds. *Id.* at 11. After many years of research, Boehringer scientists invented the novel compound—linagliptin—in a class known as DPP-IV inhibitors. *Id.* No DPP-IV inhibitors were approved by the FDA for treating T2DM when linagliptin was discovered, or for several years afterward.

After developing the linagliptin compound, Boehringer continued to conduct animal studies and clinical trials and further discovered that 2.5 mg and 5 mg doses of linagliptin—which

were not initially expected to have any clinical effect—were therapeutically effective, and that these same doses could safely be administered to patients with any degree of renal impairment. D.I. 618 at 11-13. As a result of Boehringer’s work, linagliptin (marketed under the brand names Tradjenta® and Jentadueto®) is the only drug in its class approved for use in all patients, including those with all levels of renal impairment, without any need to adjust the dose. D.I. 613, 6/5/18 Trial Tr. at 80:4-8. Because of this, linagliptin is physicians’ DPP-IV inhibitor of choice for patients with renal impairment. D.I. 610, 6/13/18 Trial Tr. 1324:7-1325:1.

The United States Patent Office awarded Boehringer three patents covering the linagliptin compound: the ‘955, ‘648, and ‘541 patents. *See* D.I. 6-1, U.S. Patent No. 7,407,955; D.I. 6-2 U.S. Patent No. 8,119,648; D.I. 6-3 U.S. Patent No. 8,178,541. The Patent Office also granted Boehringer the ‘927 and ‘859 patents directed to methods of treating T2DM using the 2.5 mg and 5 mg doses of linagliptin in combination therapy, and the ‘156 and ‘526 patents, directed to methods of administering linagliptin to patients with renal impairment in the same doses administered to patients with normal kidney function. *See* D.I. 6-4, U.S. Patent No. 8,673,927; Civ. A. No. 3:16-cv-00852 D.I. 15-1, U.S. Patent No. 9,173,859; D.I. 6-6 U.S. Patent No. 8,853,156; Ex. 1, U.S. Patent No. 9,486,526.

## **II. Linagliptin Enjoyed Great Success in the Marketplace**

The FDA approved linagliptin for the treatment of T2DM under the brand name Tradjenta® in May 2011. D.I. 618 at 5. The FDA approved Jentadueto®—a single-pill combination of linagliptin and metformin (the standard first-line therapy for T2DM)—in February 2012. *Id.* at 6. Despite linagliptin being the third DPP-IV inhibitor to enter the U.S. market, Tradjenta® and Jentadueto® have surpassed the second entrant and have steadily gained market share. *Id.* at 56-57. [REDACTED] [REDACTED] [REDACTED] [REDACTED]. D.I. 657 at

1; D.I. 658, ¶ 3. The compound patents, among others, are listed in the Orange Book for Tradjenta<sup>®</sup> and Jentadueto<sup>®</sup>.

III. [REDACTED]  
[REDACTED]

Following this success, HEC and eleven other generic drug manufacturers sought approval to market generic versions of Tradjenta<sup>®</sup> and Jentadueto<sup>®</sup>, before the expiration of Boehringer's patents, resulting in the underlying lawsuit<sup>2</sup> involving the compound patents and the '927, '859, and '156 patents. *See generally* D.I. 6; Civ. No. 19-1772 (D. Del.), D.I. 1. Ten of the twelve generic manufacturers did not even attempt to challenge the compound patents—their ANDAs contained Paragraph III certifications for the compound patents. *See generally* D.I. 6. “[F]iling a Paragraph III certification ... serves as recognition ... that the patent is valid and enforceable.” *Apotex Inc. v. Eisai Inc.*, No. 1:09-cv-477, 2010 WL 3420470, at \*11 n.4 (M.D.N.C. Aug. 27, 2010). That means that “[a]n ANDA certified under Paragraph III must, even after meeting all applicable scientific and regulatory requirements, wait for approval until the listed drug's patent expires.” *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1245 (Fed. Cir. 2000). [REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

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<sup>2</sup> One of the generic manufacturers, Macleods, filed its ANDA later and was not part of the underlying lawsuit. Its case proceeded separately in the District of Delaware [REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Both further  
consented to being “enjoined from making, having made, using, selling, offering to sell, importing  
or distributing” their respective ANDA products. D.I. 517, ¶ 3; D.I. 546 ¶ 3. [REDACTED]

[REDACTED]

IV. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED] ■ [REDACTED]

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[REDACTED]

**V. The Federal Circuit Reversed This Court’s Decision On The ‘156 Patent, And Affirmed On The Claims of the ‘927 and ‘859 Patents**

Only two defendants—Mylan and Aurobindo—proceeded to trial, and only on two patents: the ‘927 and ‘859 patents. After a bench trial, this Court concluded that the litigated claims of the ‘859 and ‘927 patents were invalid. D.I. 620 at 58; *see id.* at 2; *see also* D.I. 619. Importantly, because both defendants filed Paragraph III certifications conceding that Boehringer’s compound

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<sup>3</sup>

[REDACTED]

<sup>4</sup>

[REDACTED]

patents were valid and infringed, the compound patents were *not* part of that trial. *See generally*, D.I. 6. The ‘156 patent was not part of the trial either, because this Court had previously declared that patent invalid on a motion to dismiss. D.I. 388.

Boehringer appealed this Court’s decisions on the ‘859, ‘927 and ‘156 patents, and, in February 2020, also filed a separate suit against Mylan and Aurobindo alleging infringement of the ‘526 patent.<sup>5</sup> In a March 16, 2020 opinion, the Federal Circuit reversed this Court’s dismissal of the ‘156 patent and affirmed its invalidity judgment on the ‘859 and ‘927 patents. D.I. 644 at 7, 10.

After the Federal Circuit’s mandate issued, the three parties involved in the appeal (Boehringer, Mylan, and Aurobindo) stipulated that “all” of their respective “claims and counterclaims ... regarding the ‘156 patent are dismissed with prejudice.” D.I. 649, D.I. 650. Boehringer thereafter requested that the FDA remove the ‘927 and ‘859 patents from the Orange Book. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B); Ex. 6 (Orange Book patent listing for Tradjenta®).

### ARGUMENT

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>5</sup> During the litigation, the Patent Office issued the ‘526 patent to Boehringer, but not in time for the patent to be added to the litigation without disrupting the schedule. Boehringer is currently asserting the ‘526 patent against Mylan and Aurobindo in a case pending in the Northern District of West Virginia, where Mylan is incorporated and headquartered.

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[REDACTED]

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I. [REDACTED]

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A. [REDACTED]

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As the Court has recognized, when patents are listed in the Orange Book and a generic drug manufacturer files an ANDA with a Paragraph III certification, that “effectively gives [the patent owner] the relief that would have been available to them” if they filed a lawsuit and prevailed—namely, “an injunction delaying approval of a defendant’s ANDA until expiration of all listed Orange Book patents.” *AstraZeneca*, 2014 WL 2611488, at \*5; *cf.*, *e.g.*, *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1065 (D.C. Cir. 1998) (“Mylan’s initial filing contained a paragraph III certification; this meant that Mylan conceded patent infringement, so that its ANDA could not receive FDA approval until Upjohn’s patent expired.”).

To this day, Boehringer’s compound patents remain properly listed in the Orange Book to prohibit generic competition. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] By operation of law, Boehringer has already obtained—and *continues* to maintain—injunctive relief against those parties (and eight other ANDA filers) under the compound patents. *See, e.g., AstraZeneca*, 2014 WL 2611488, at \*5.

[REDACTED]

[REDACTED]

[REDACTED]

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**B.** [REDACTED]  
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[REDACTED]

HEC glosses over this fundamental problem. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] HEC's position is utterly devoid of support.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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**C.** [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Nothing in principle or precedent supports HEC's arbitrary line drawing. [REDACTED]

## II.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Nothing

justifies any such absurd outcome.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

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### CONCLUSION

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Therefore, the Court should deny HEC's motion outright. [REDACTED]

[REDACTED]

[REDACTED].

Dated: June 22, 2020

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Respectfully submitted,

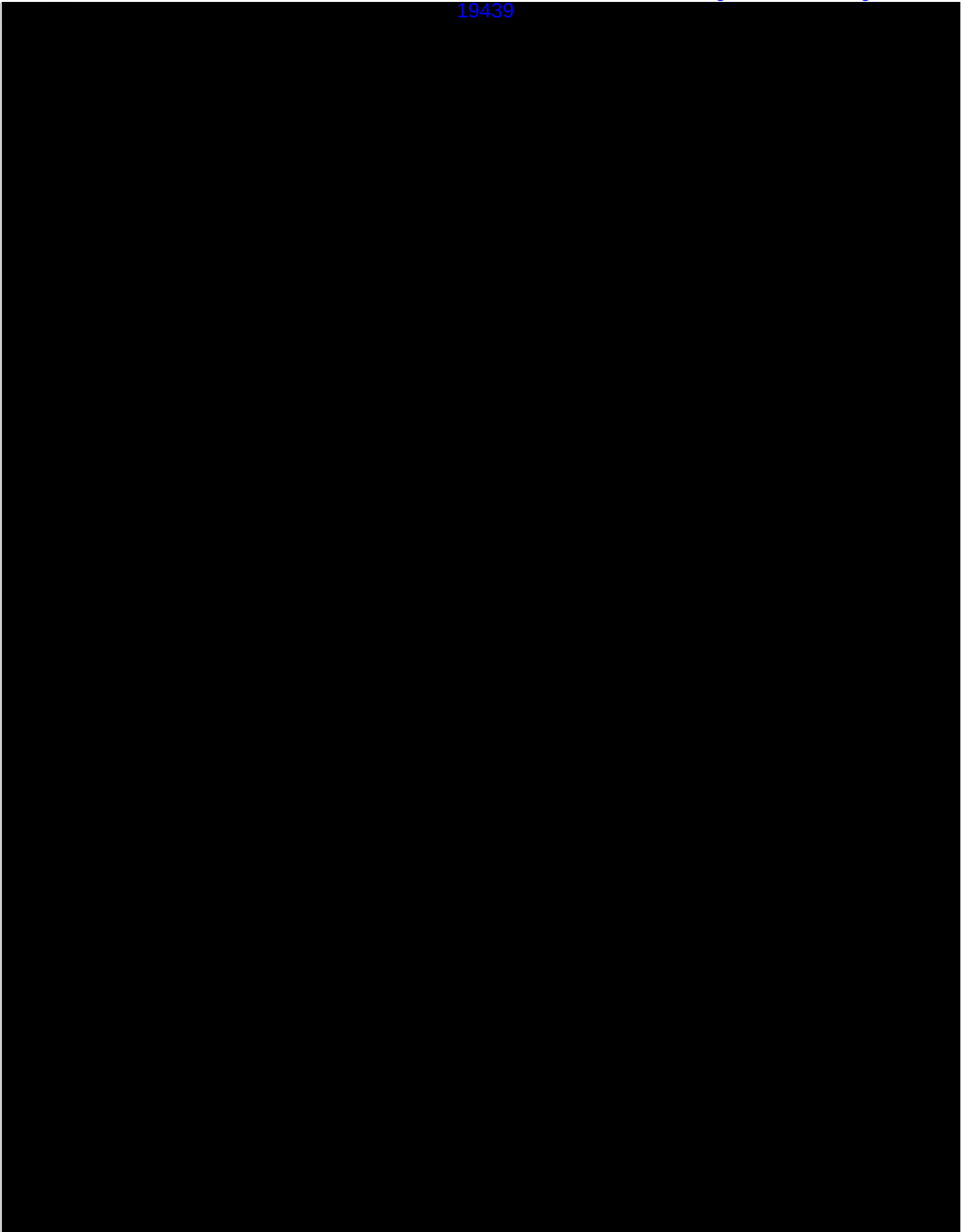
s/ Liza M. Walsh  
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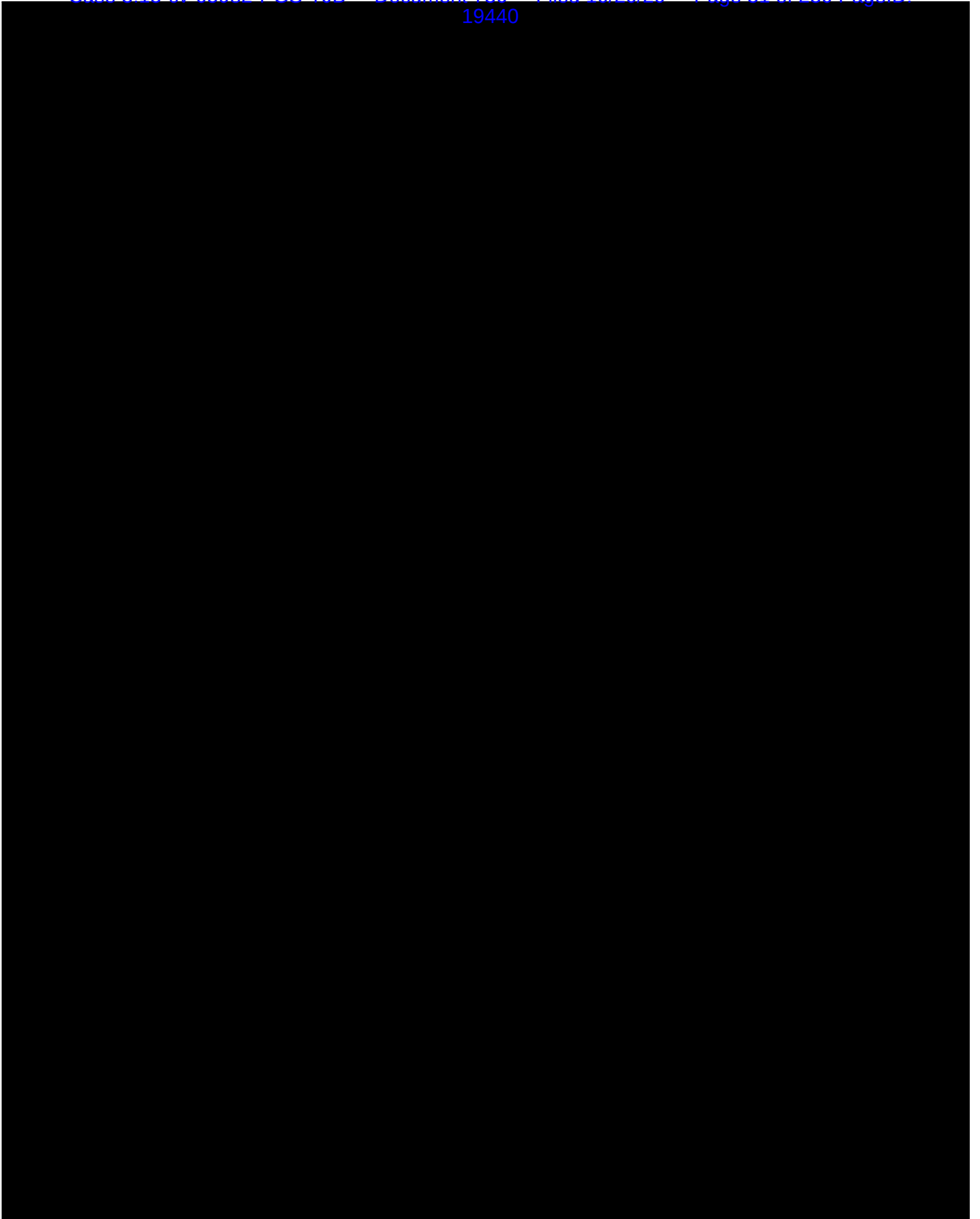
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*Counsel for Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, Boehringer Ingelheim Corporation, and Boehringer Ingelheim Pharma GmbH & Co. KG*

# **EXHIBIT 2**

## **FILED UNDER SEAL**





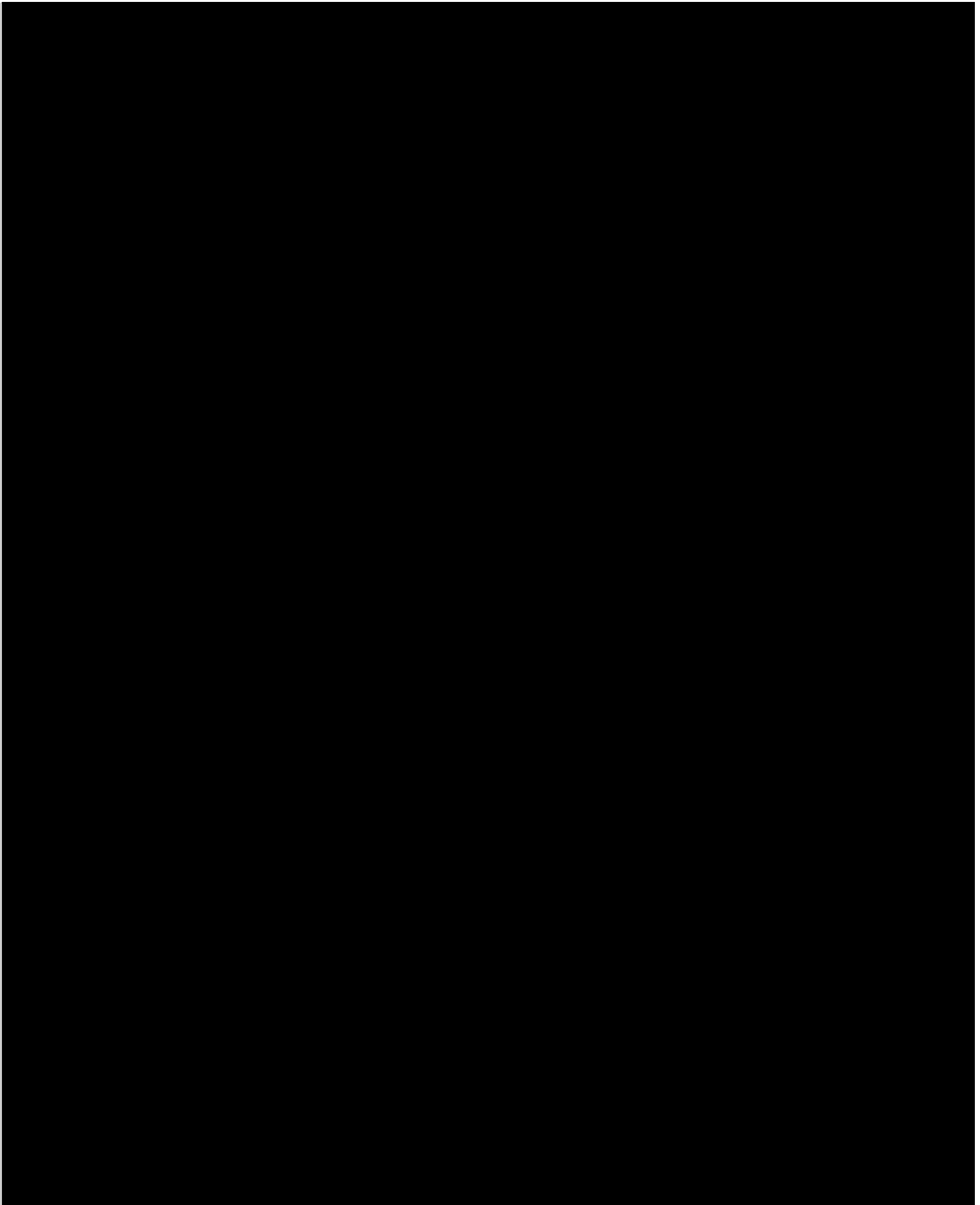


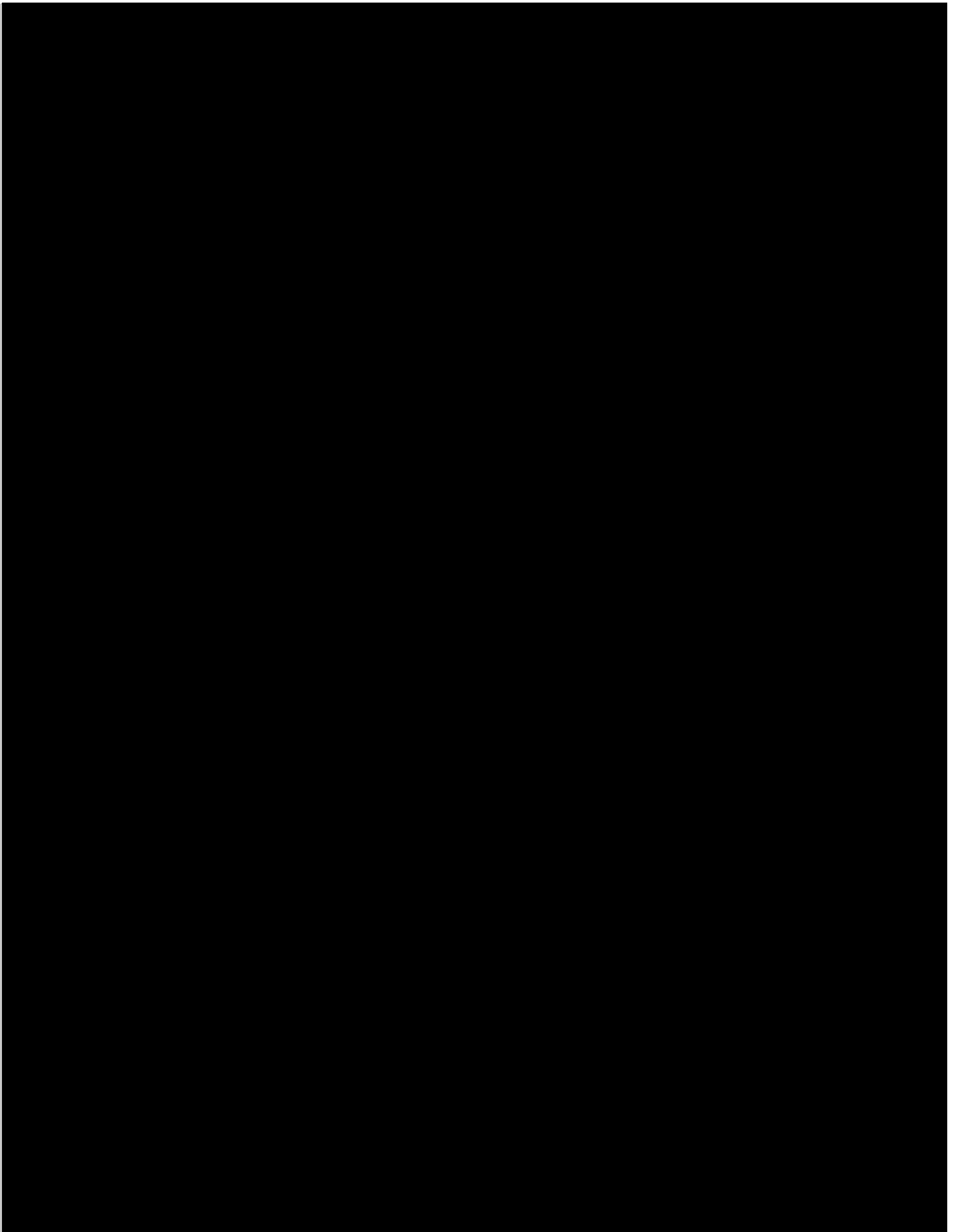


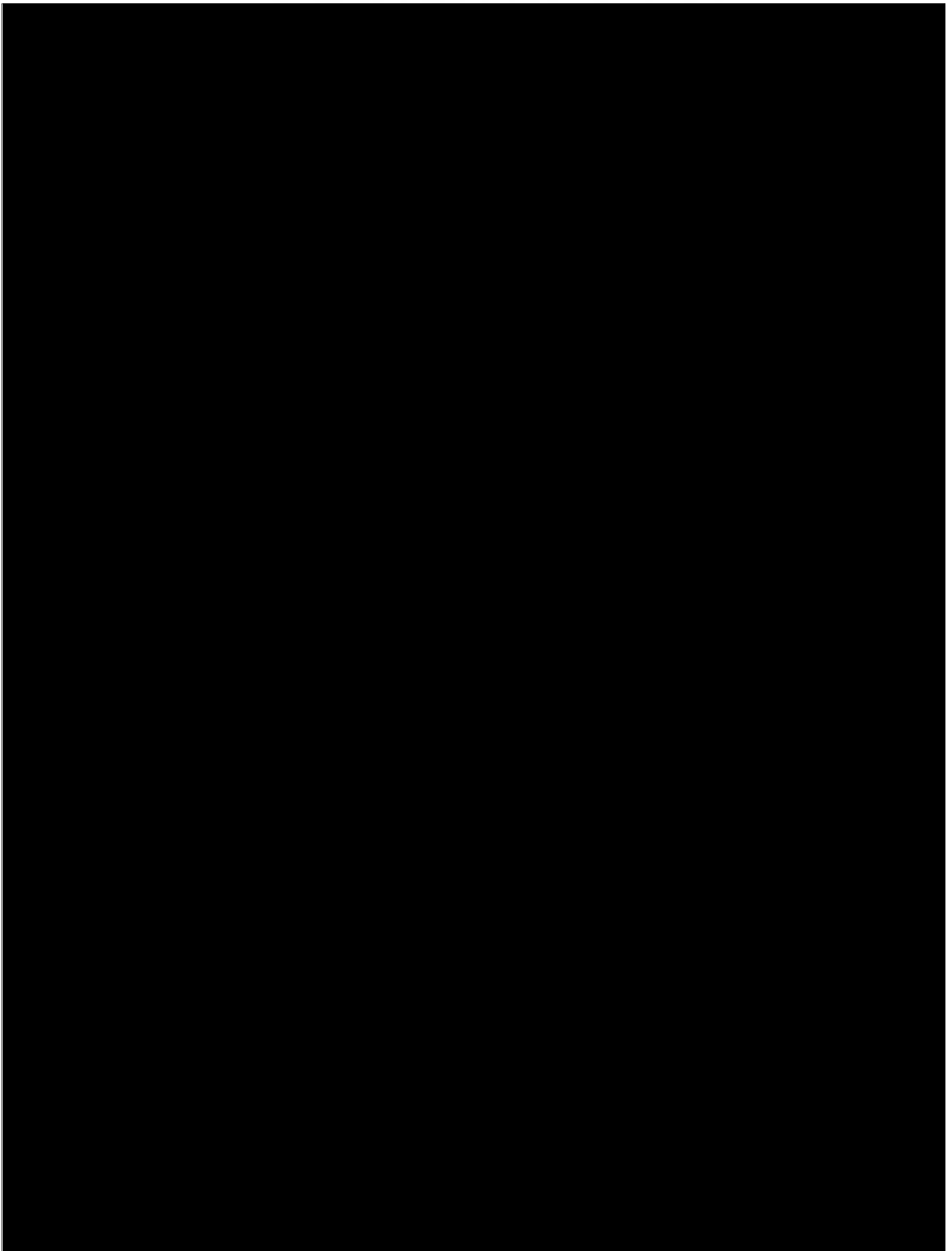


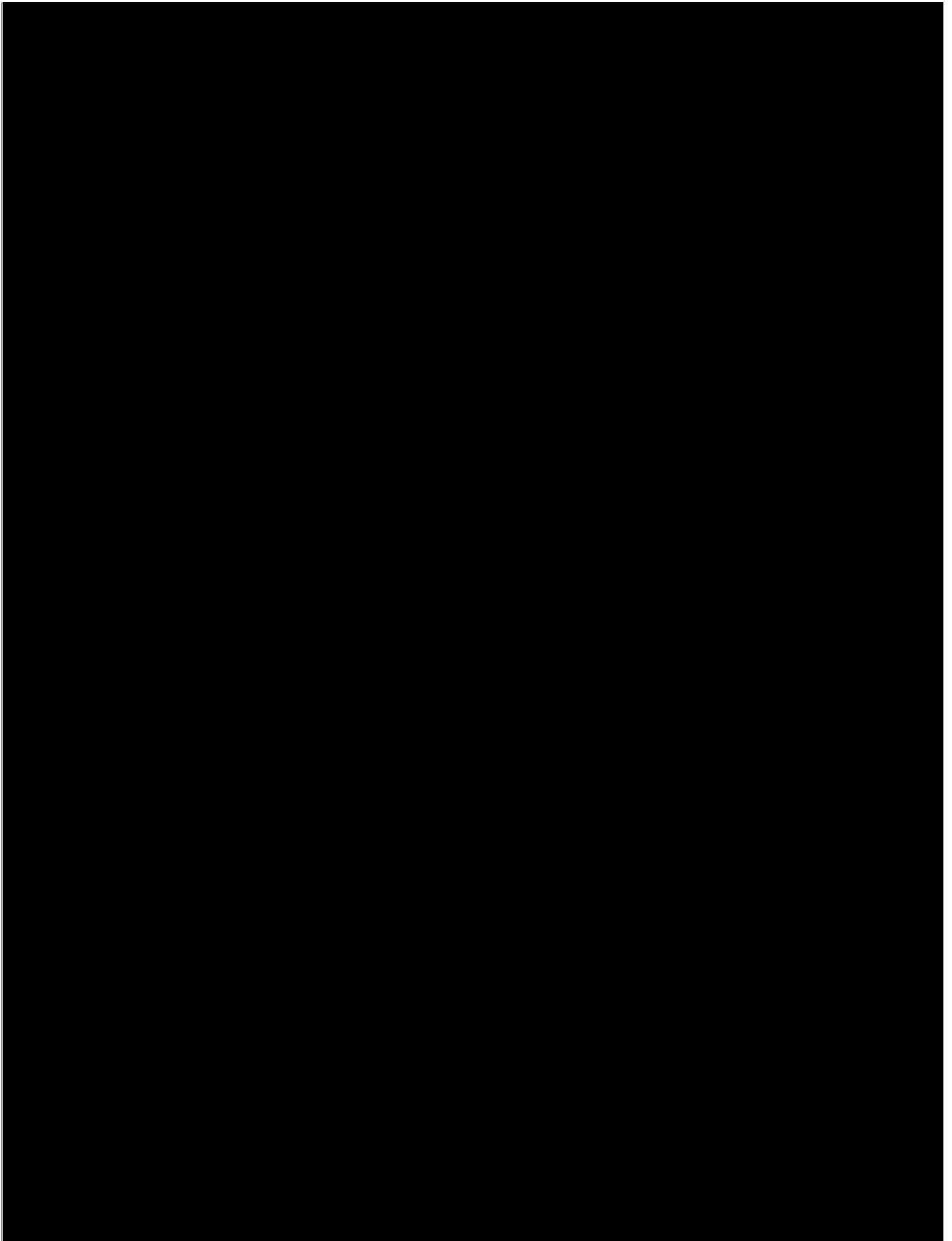


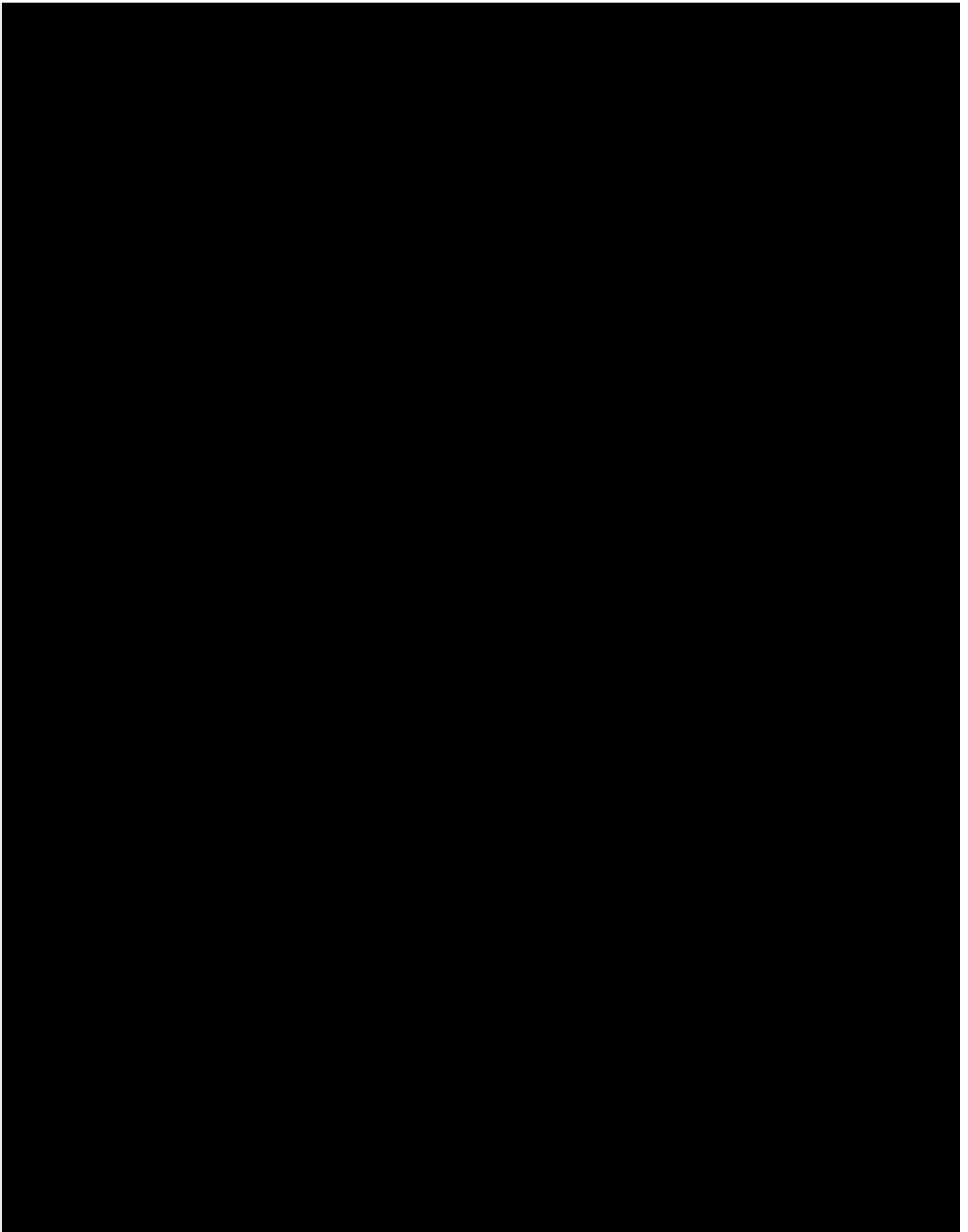




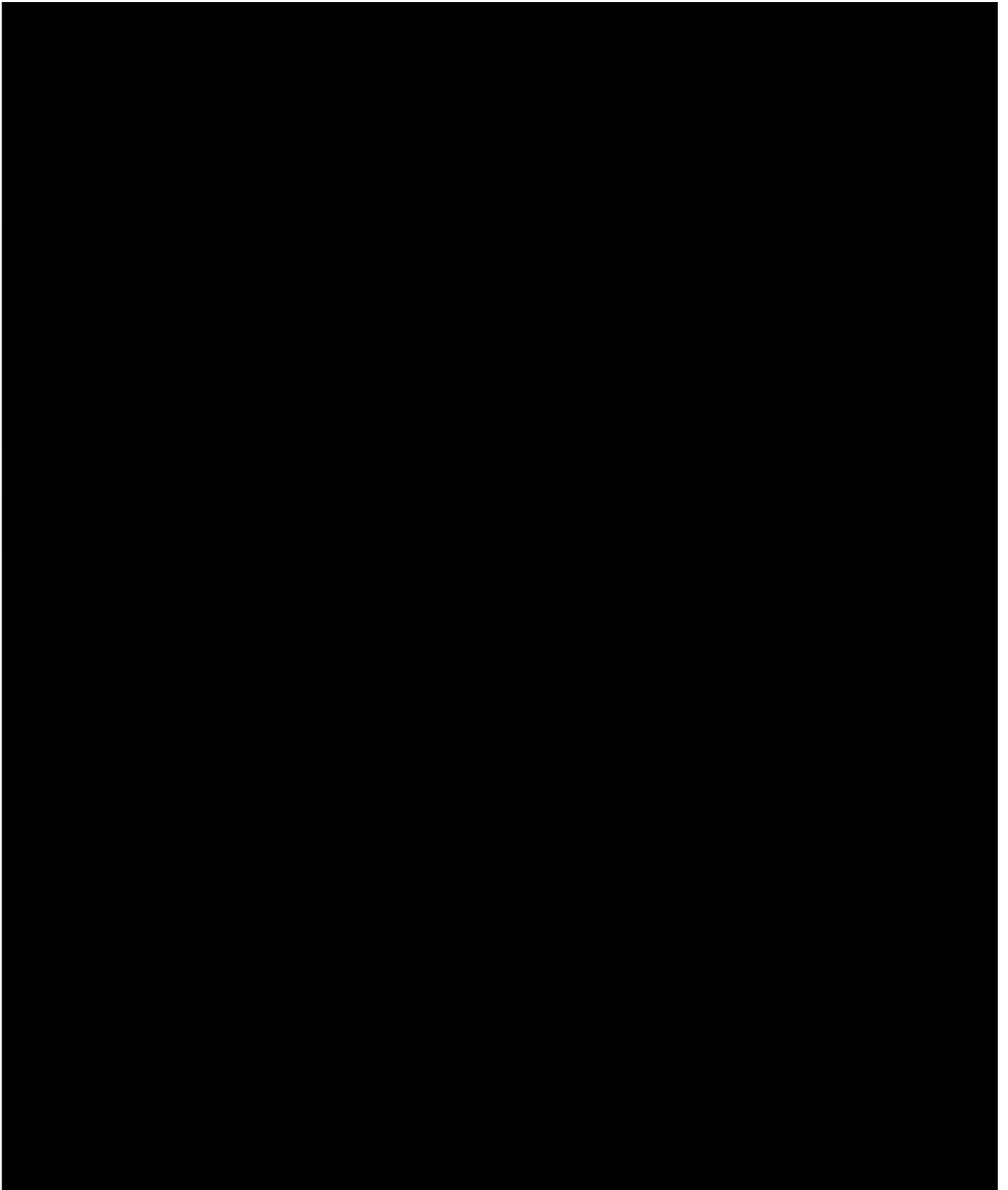


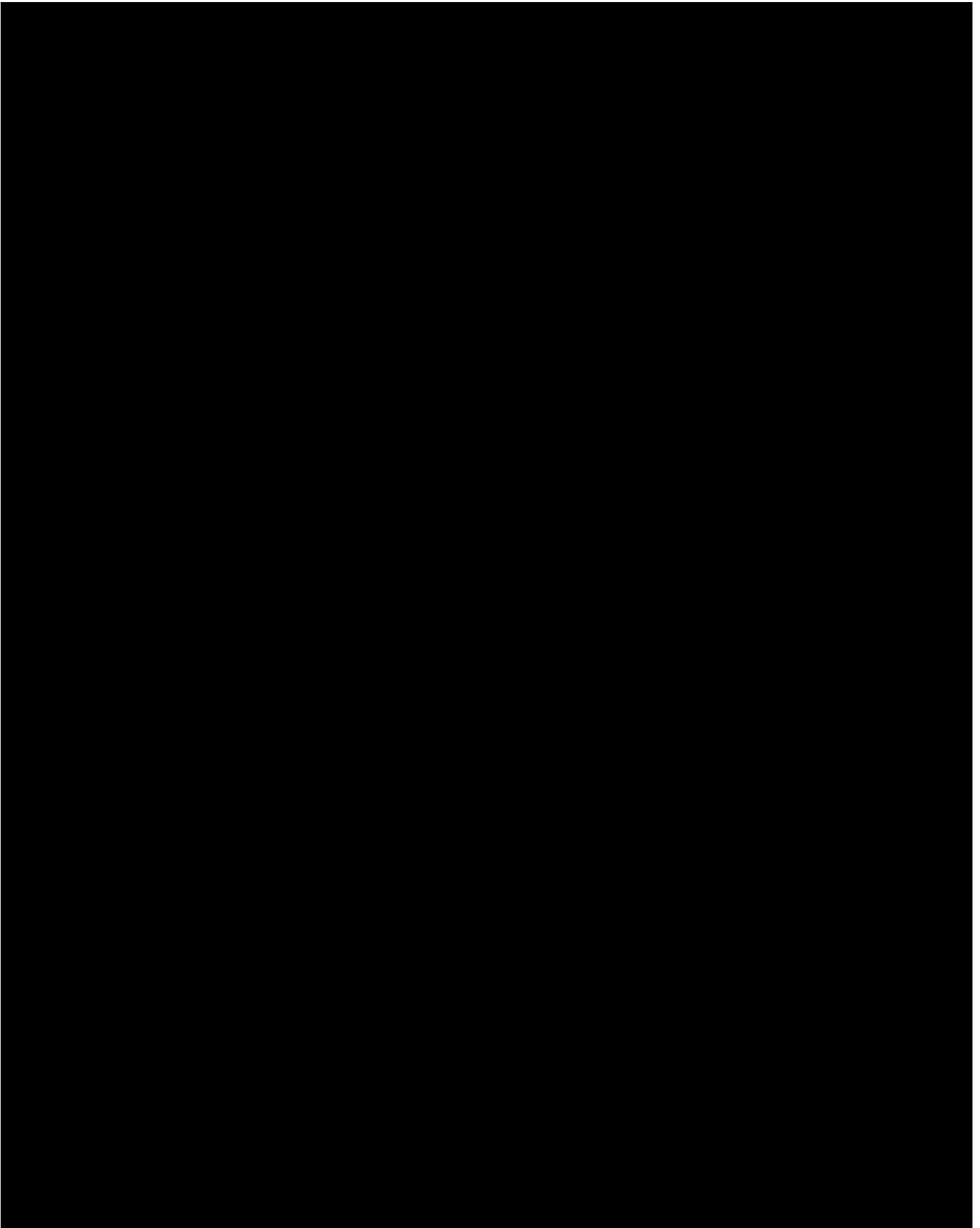


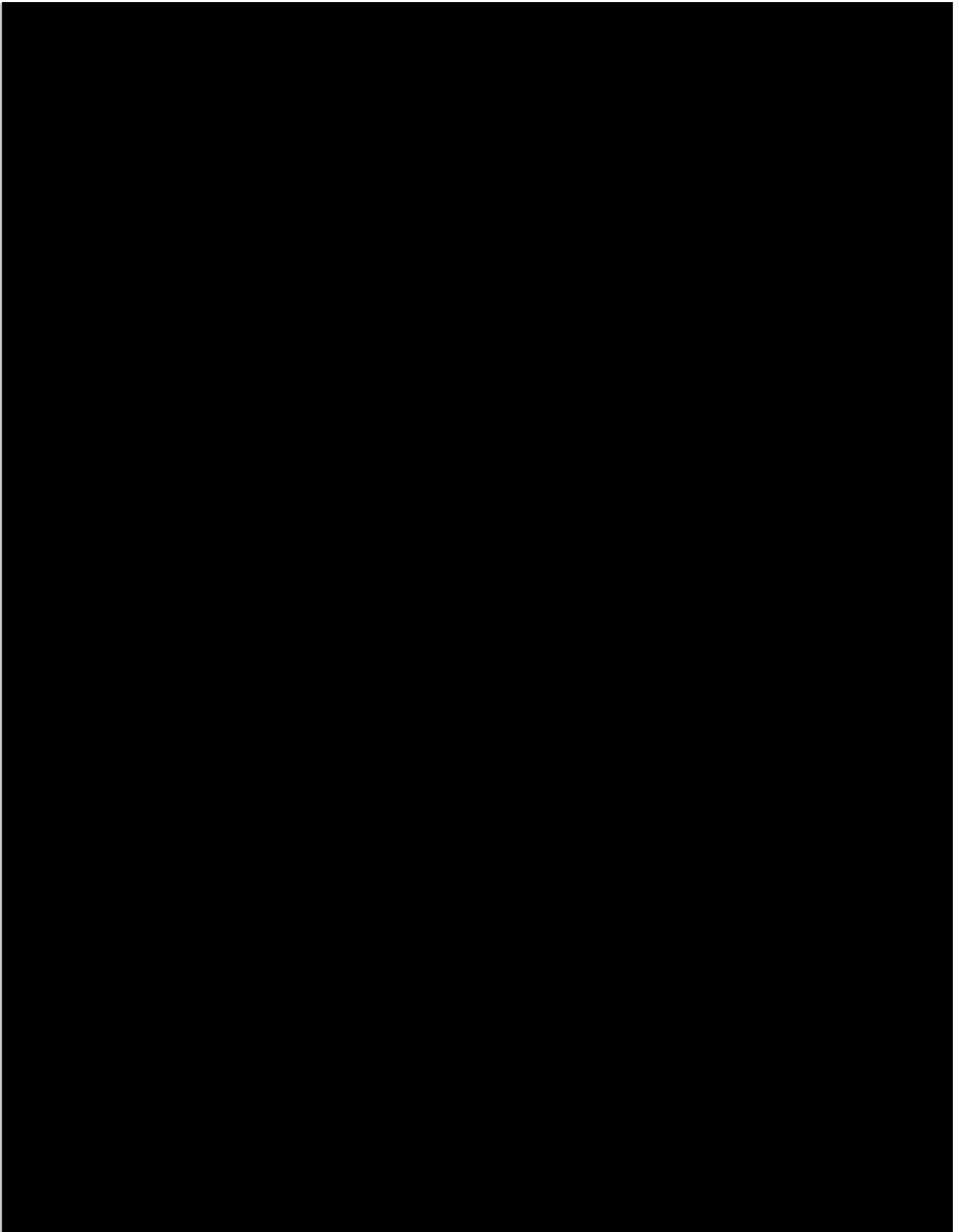


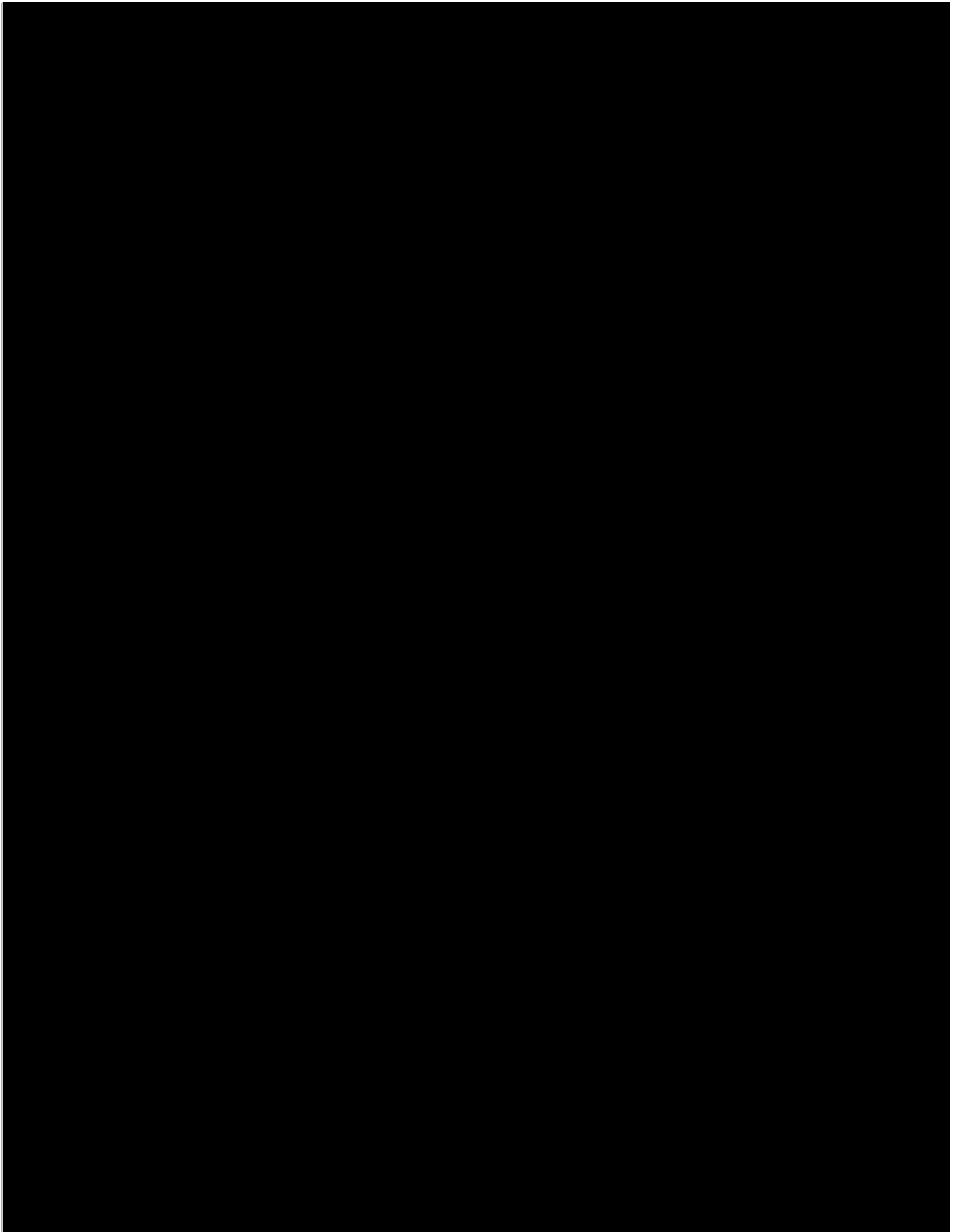


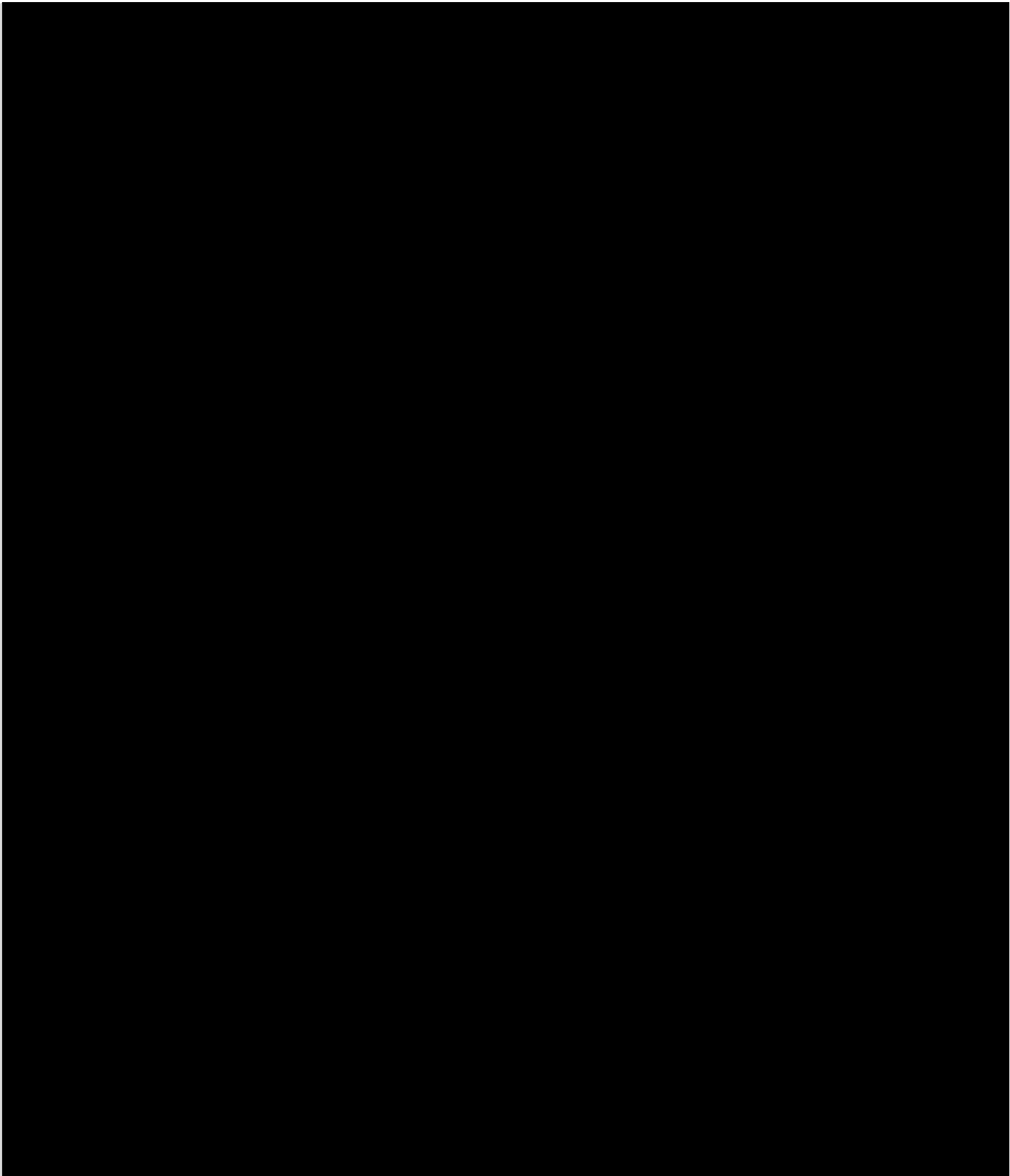


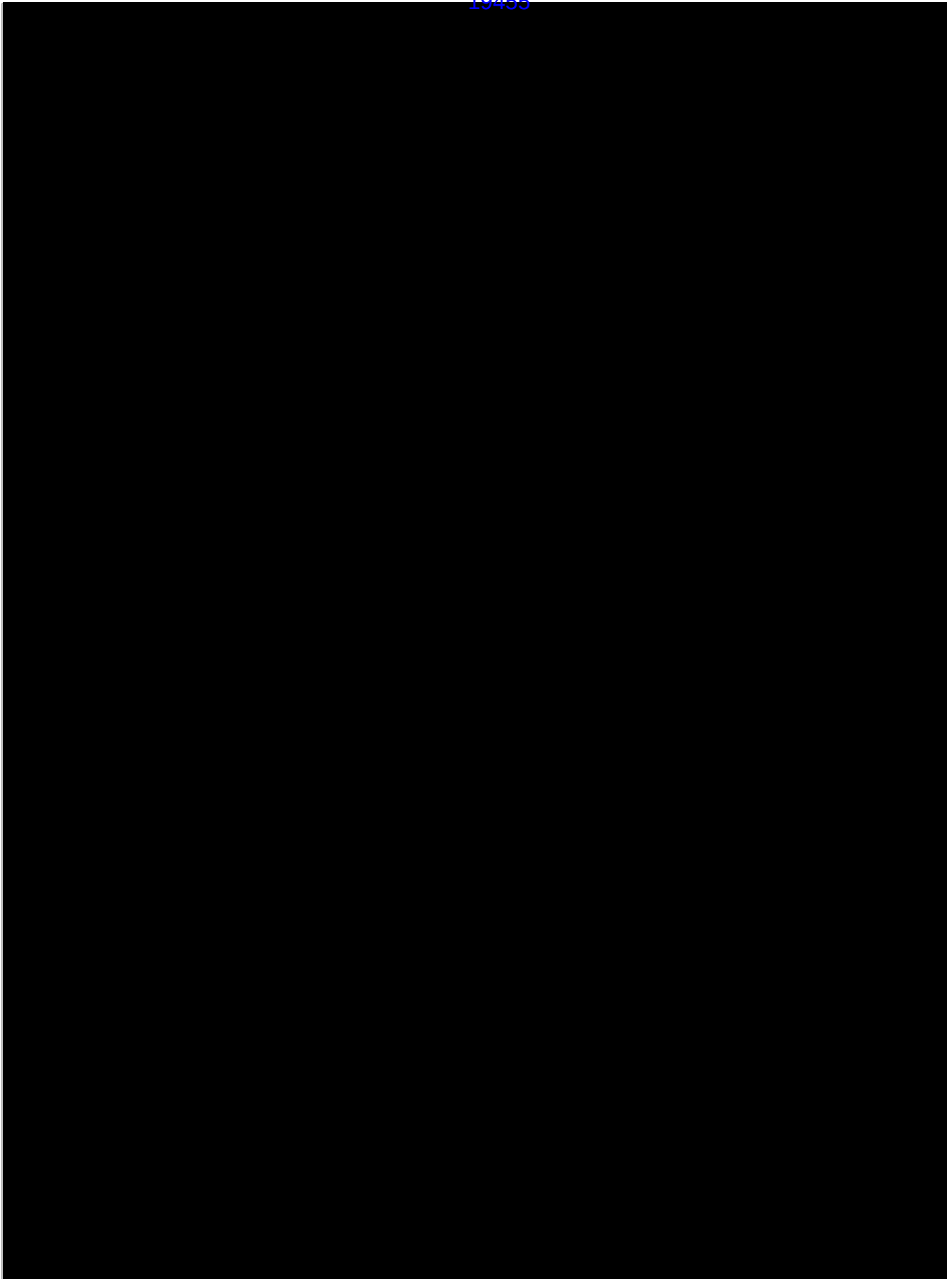




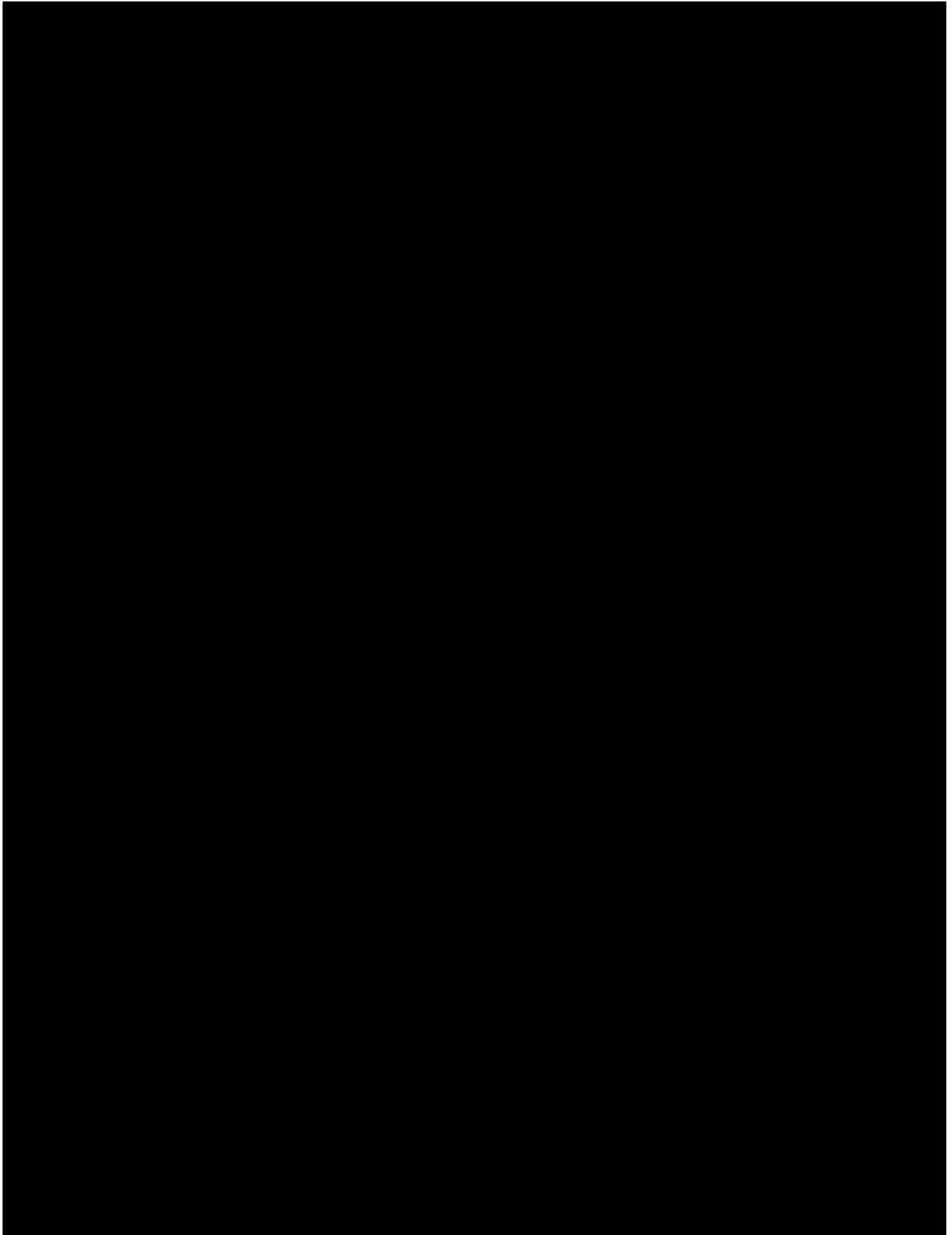




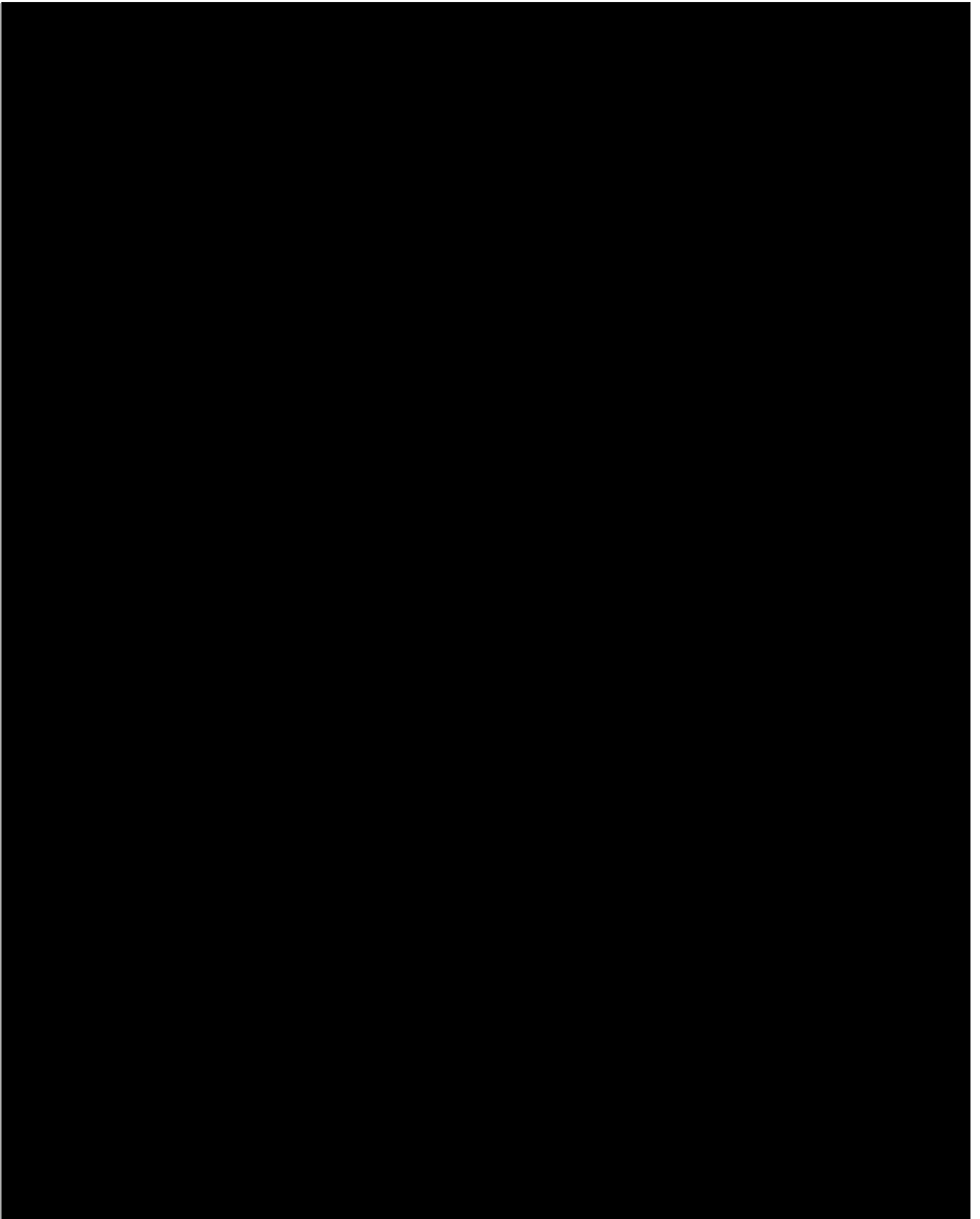


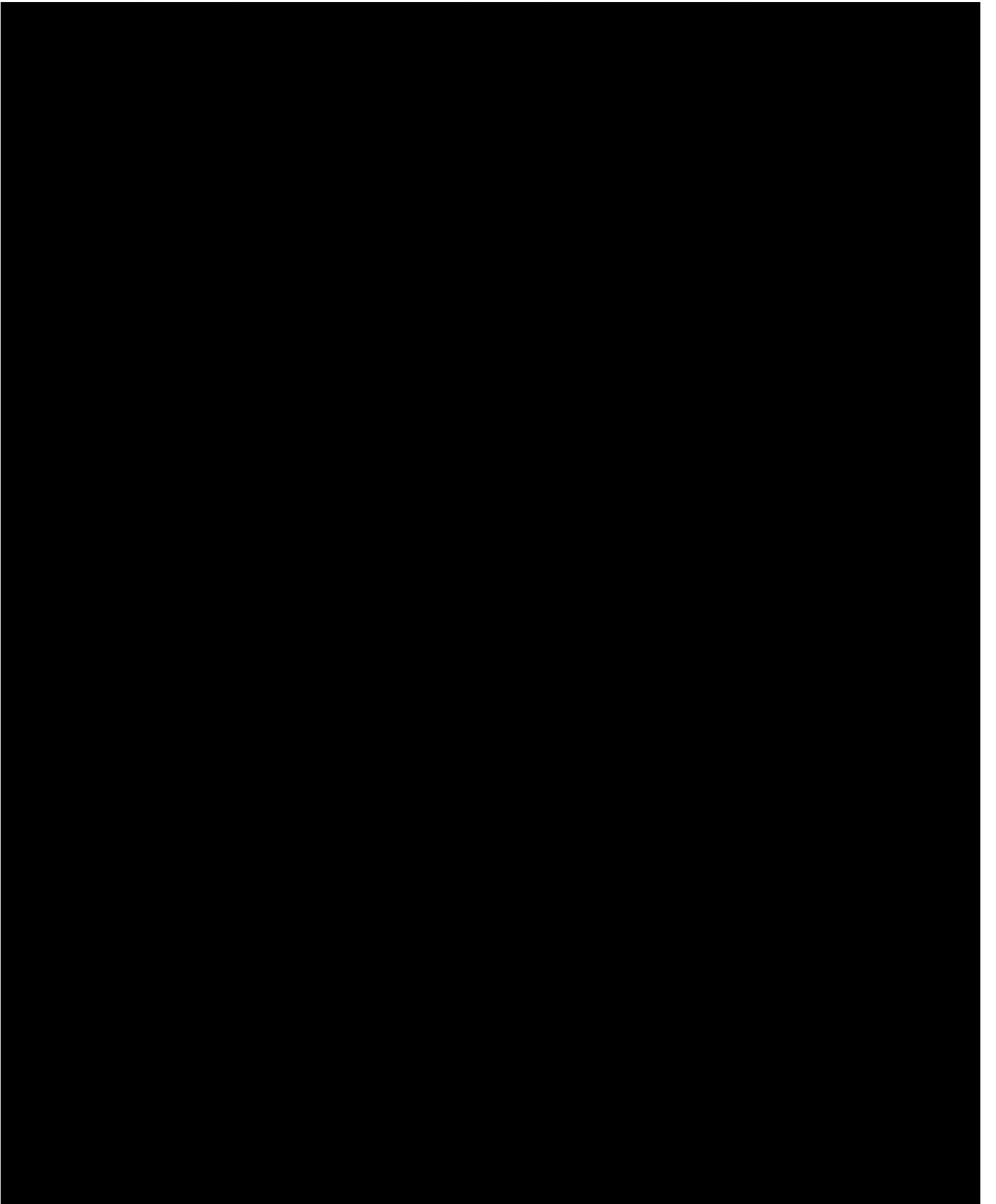




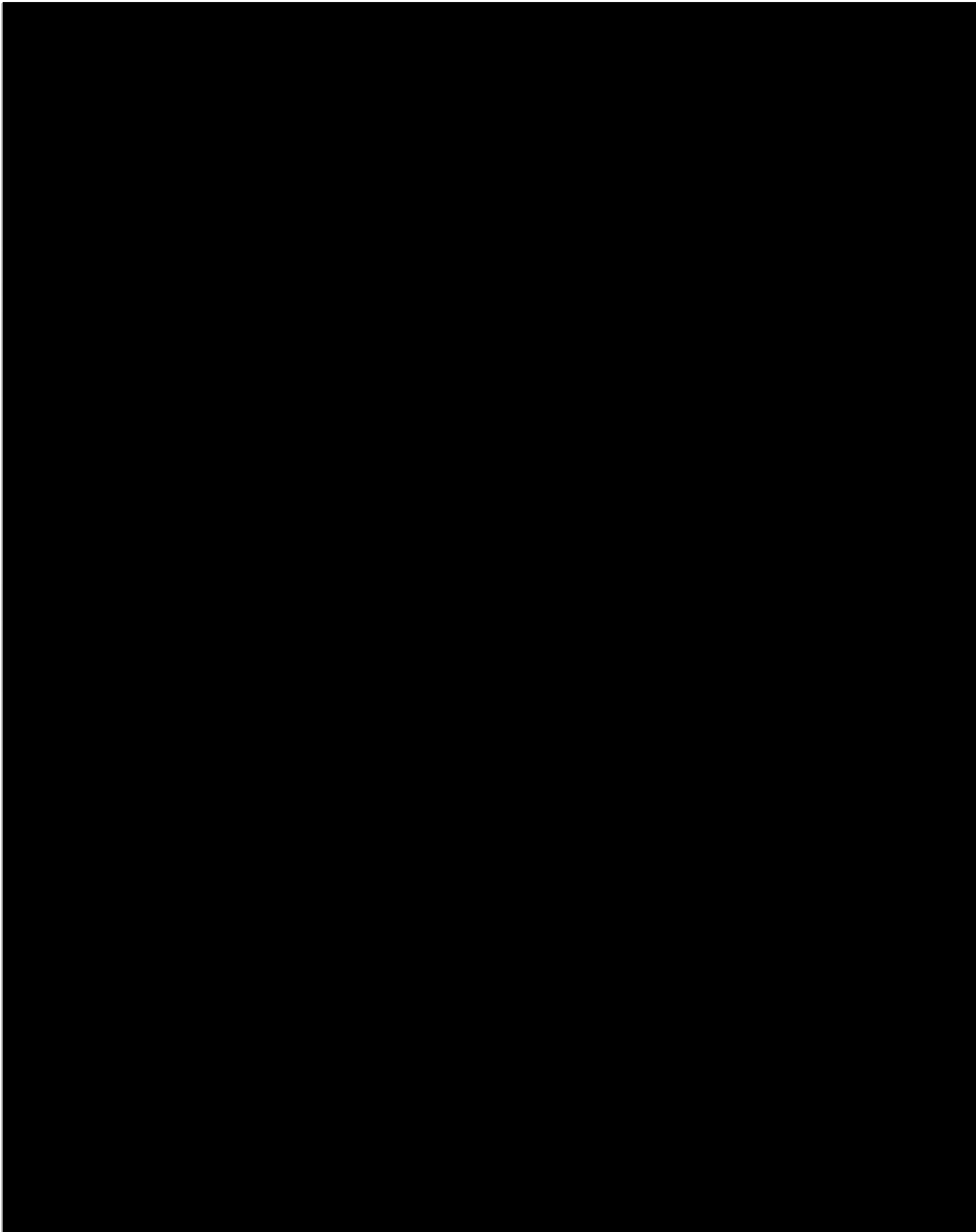


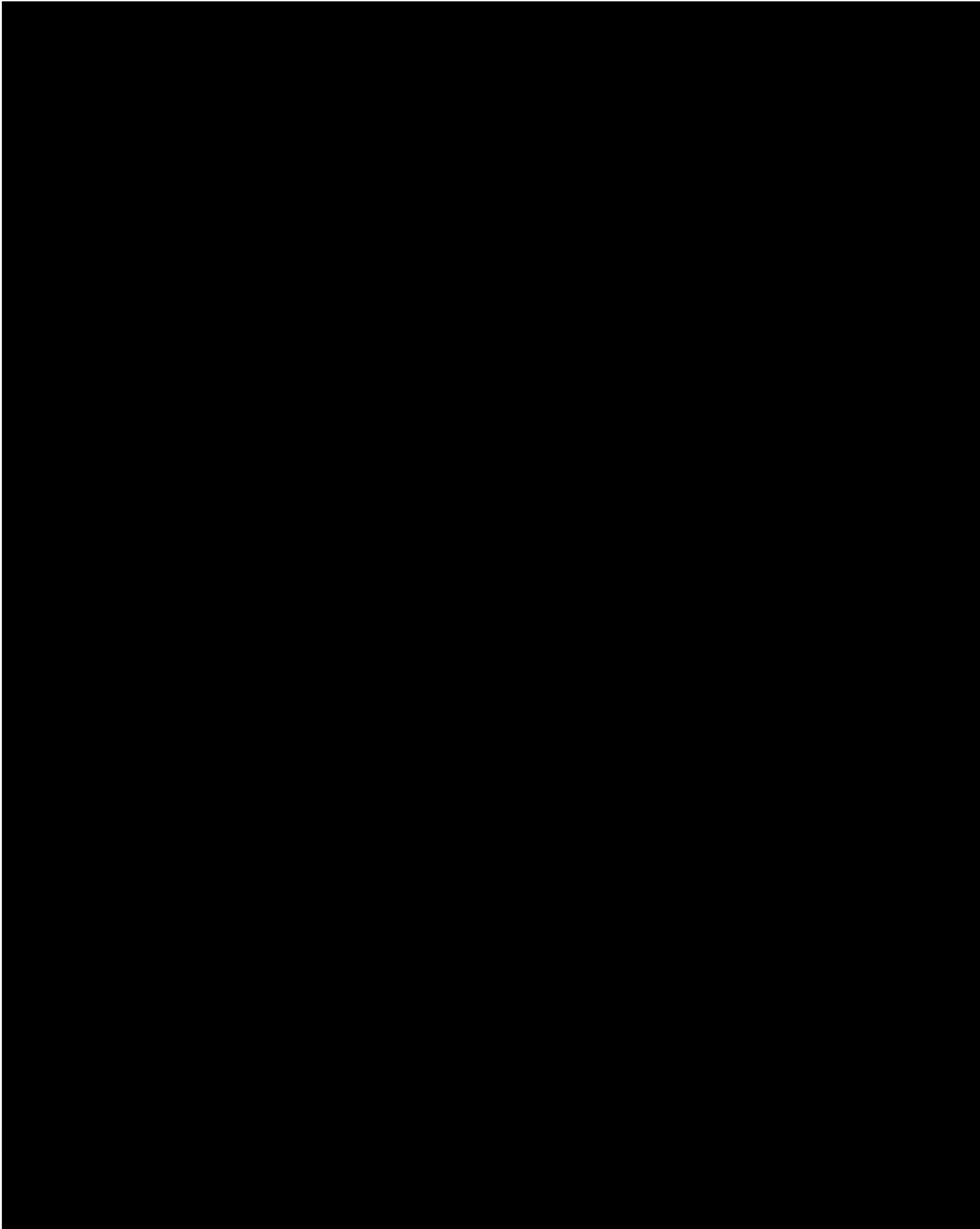




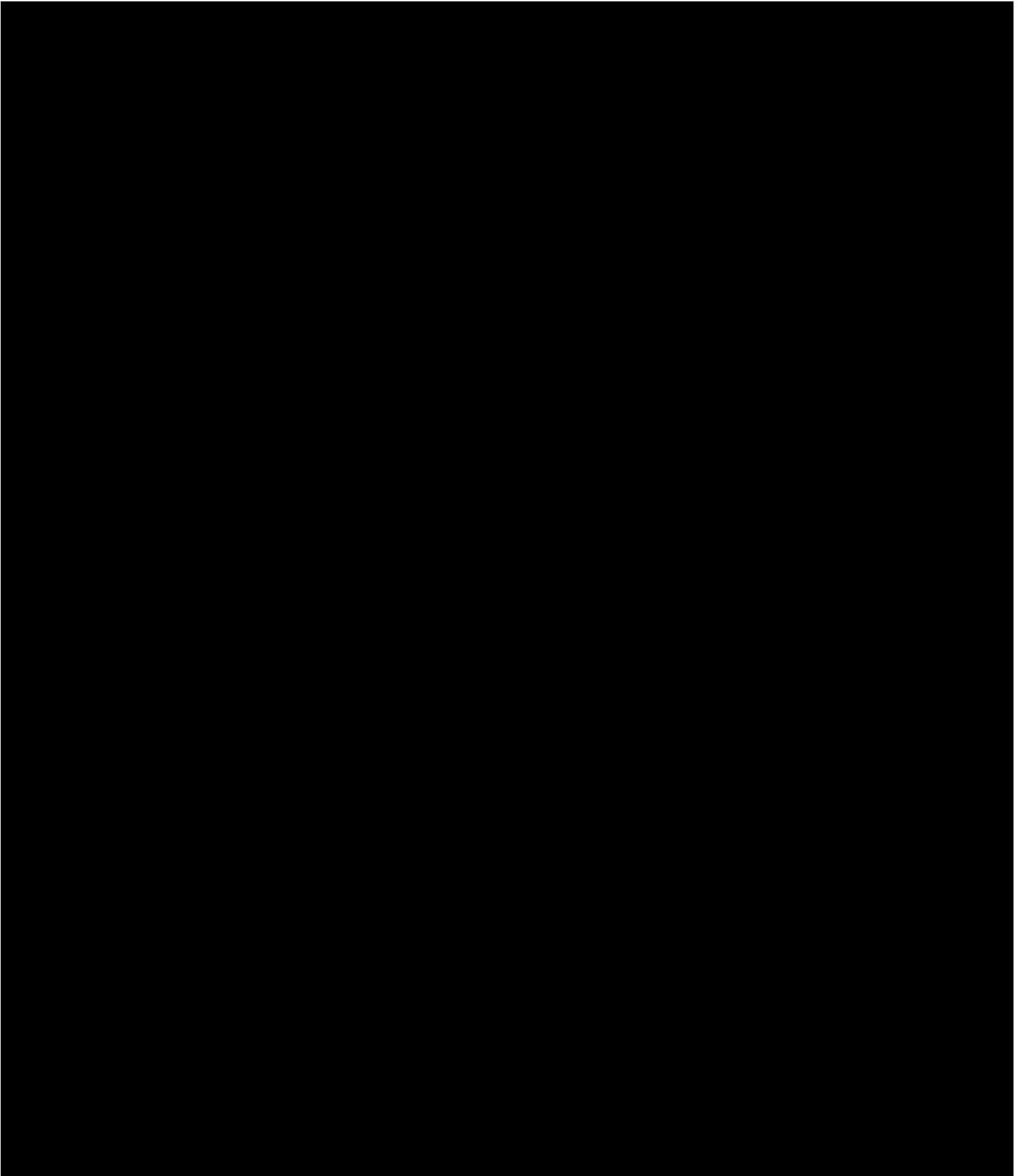


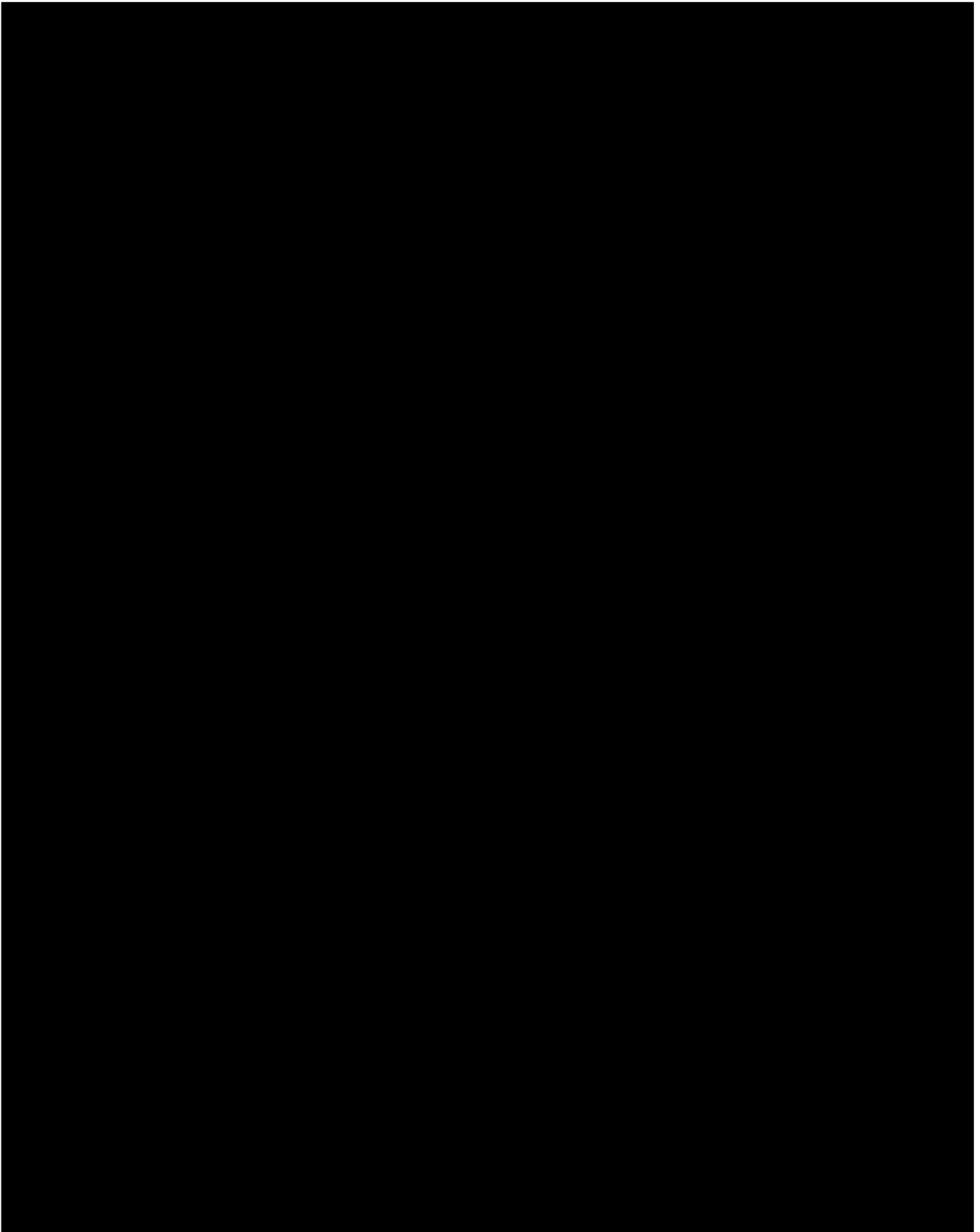




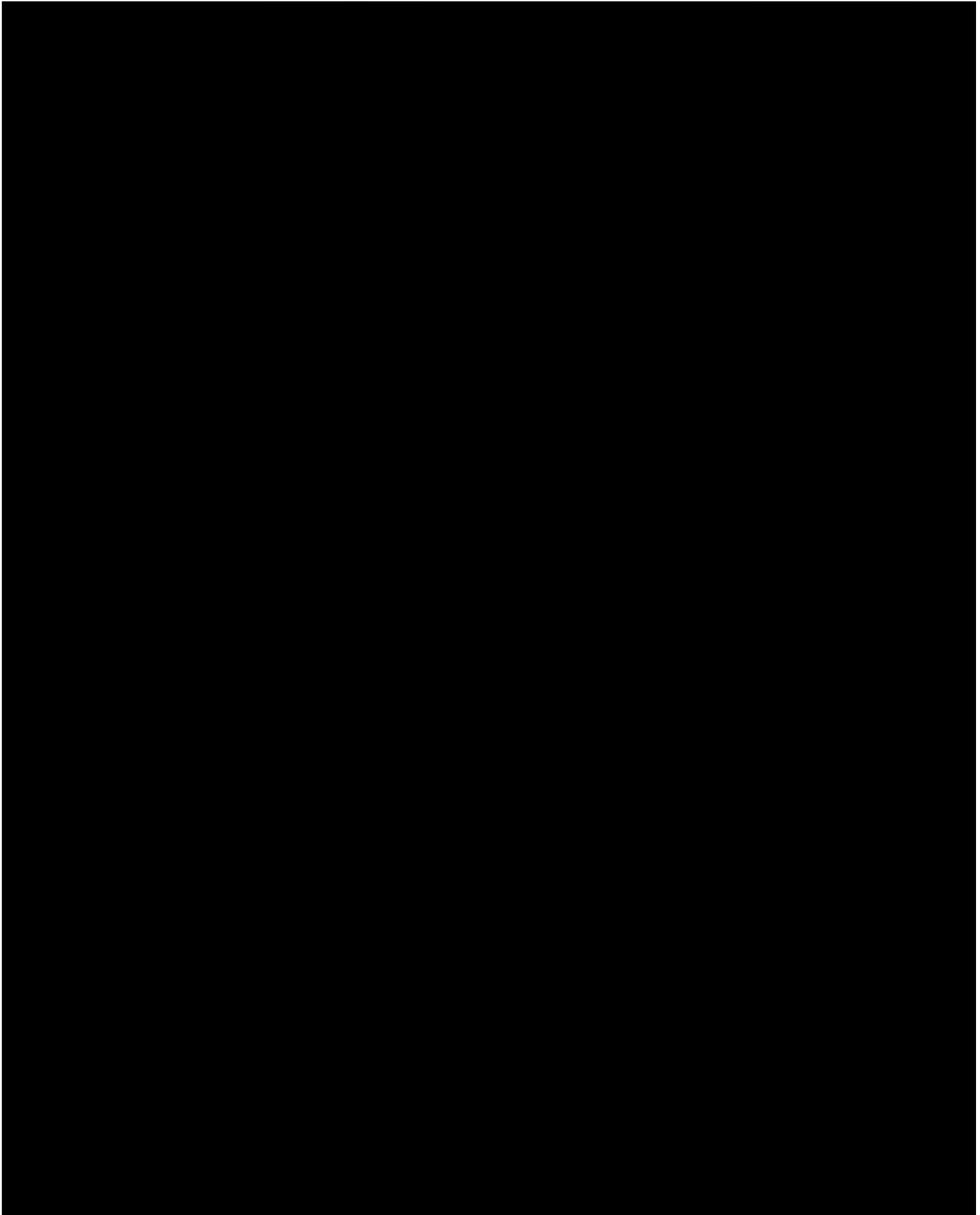


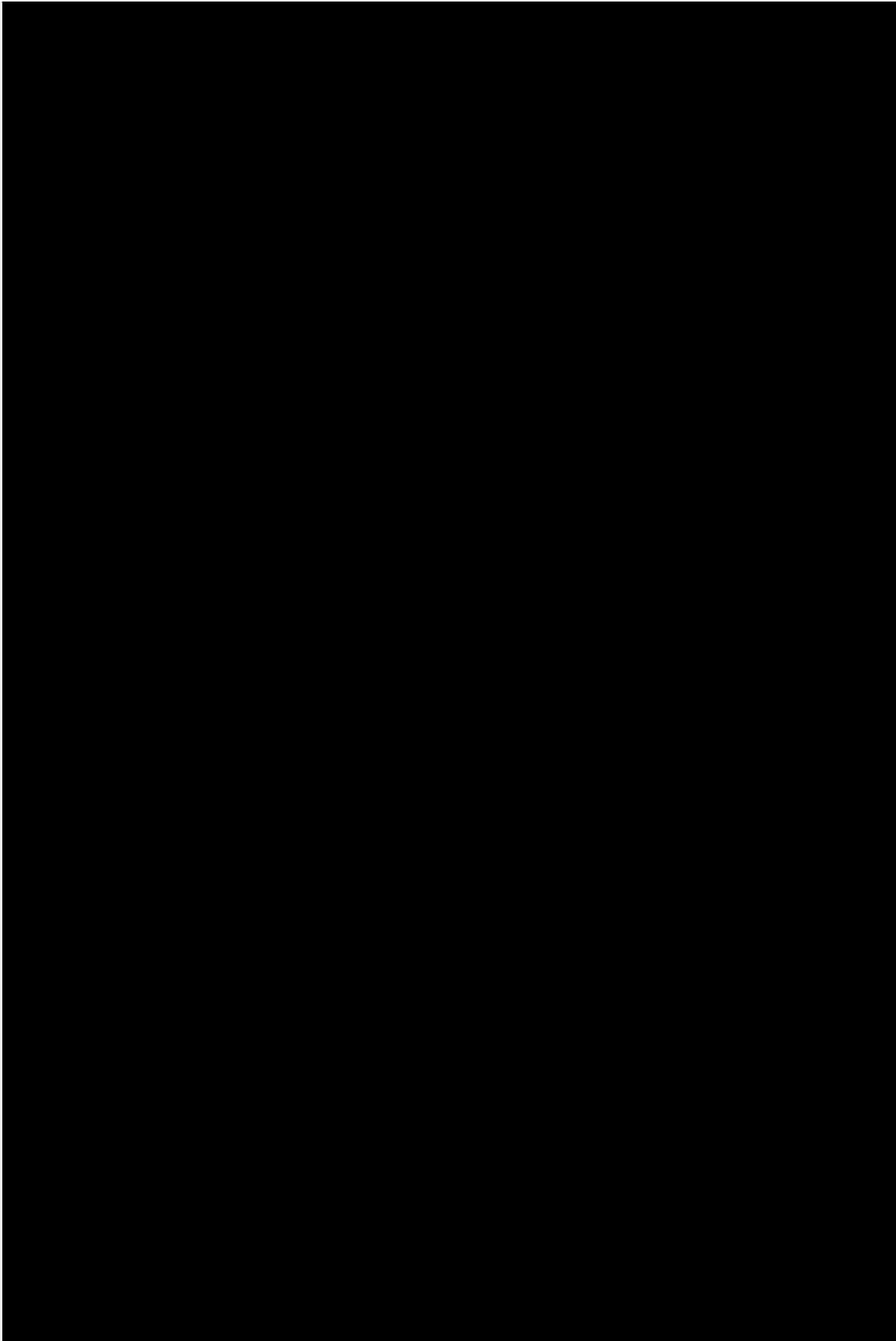


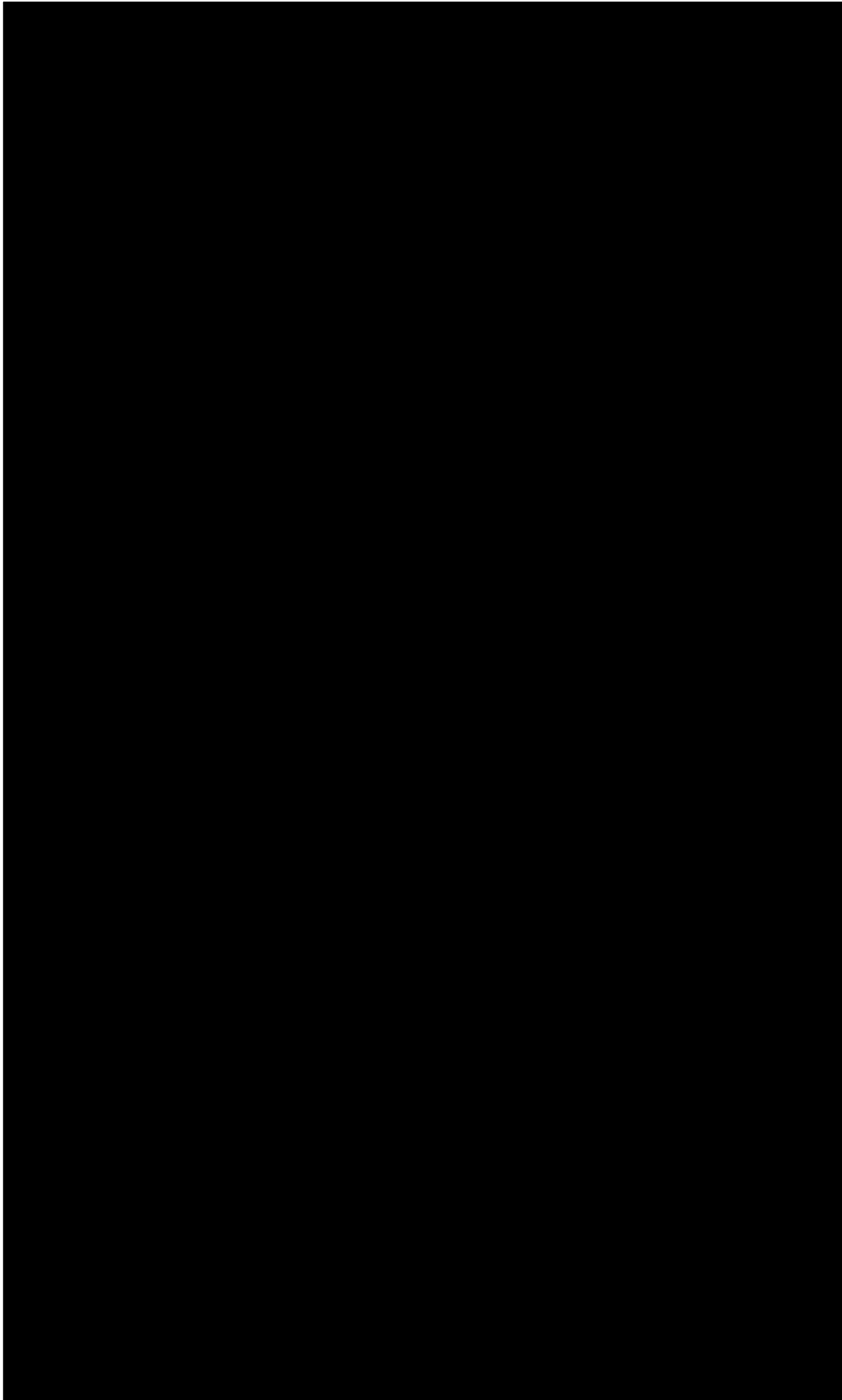


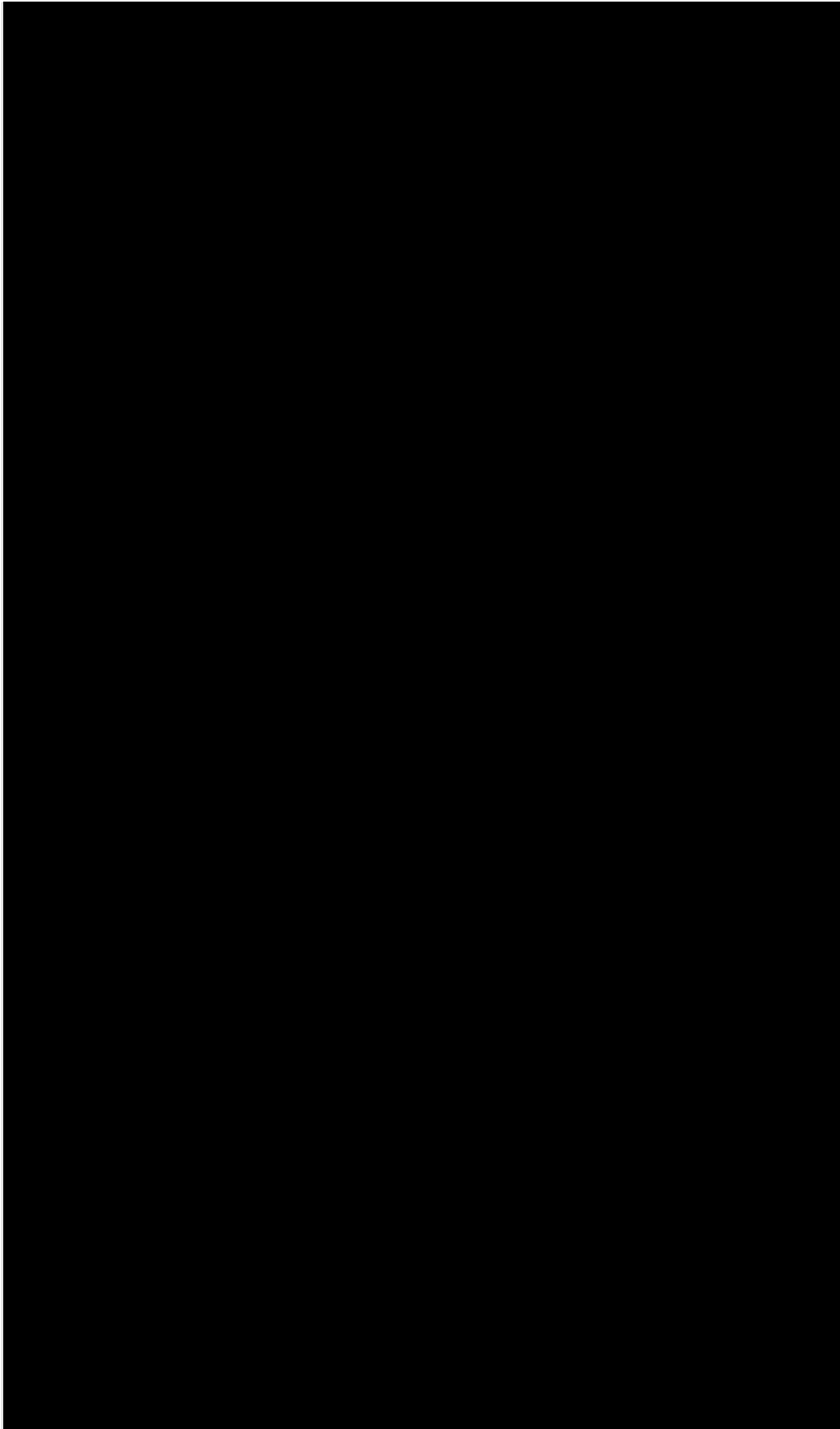


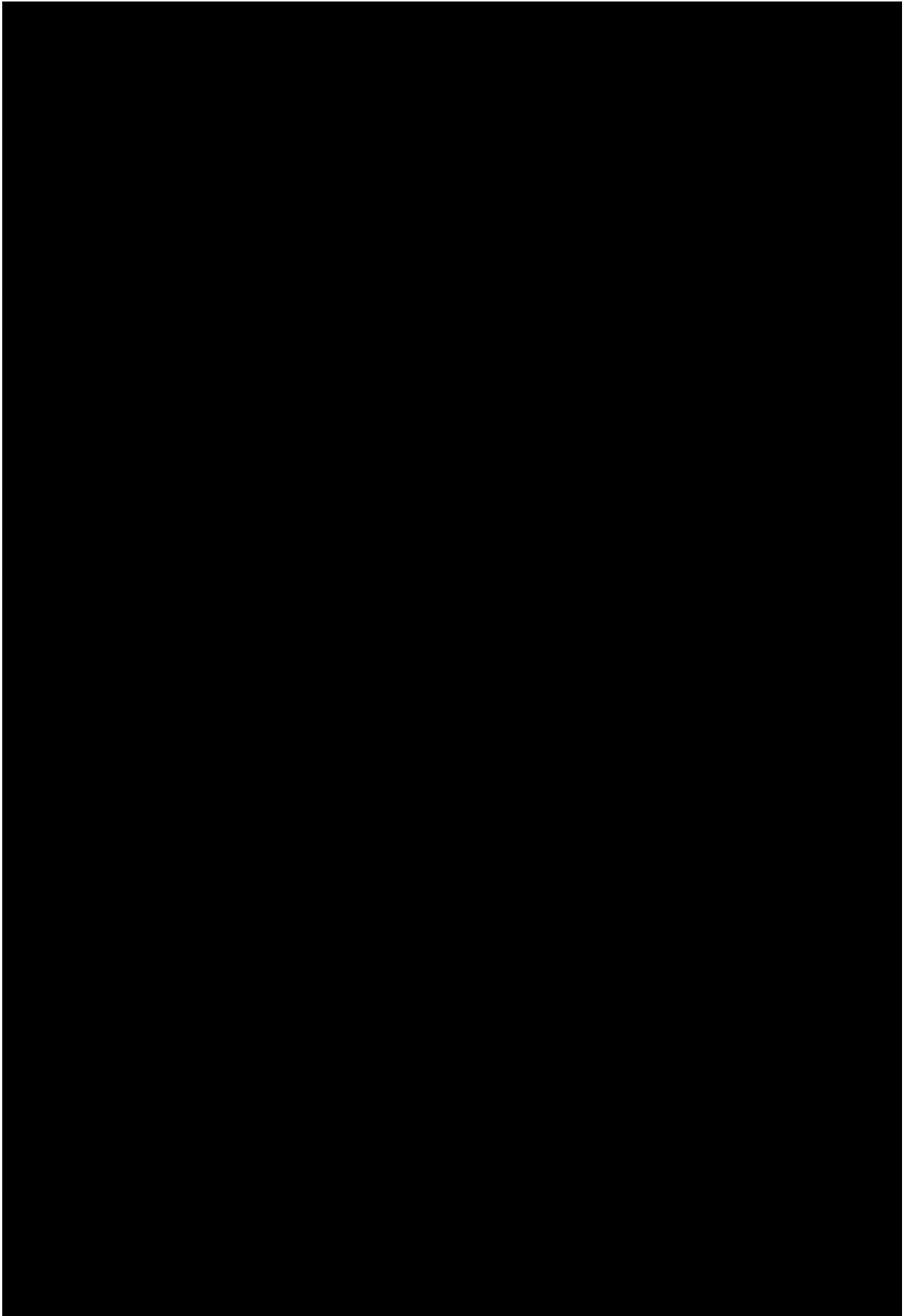


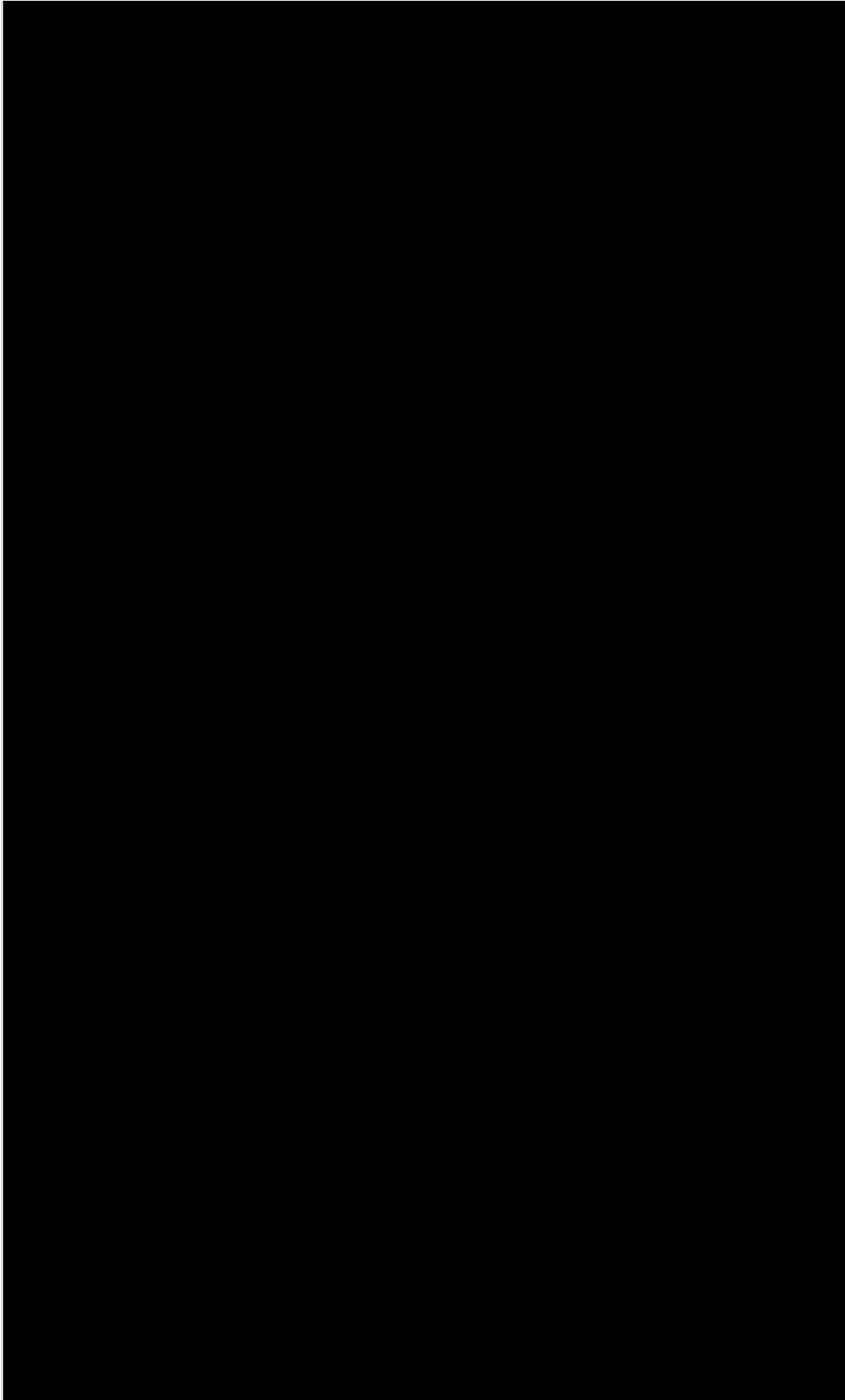


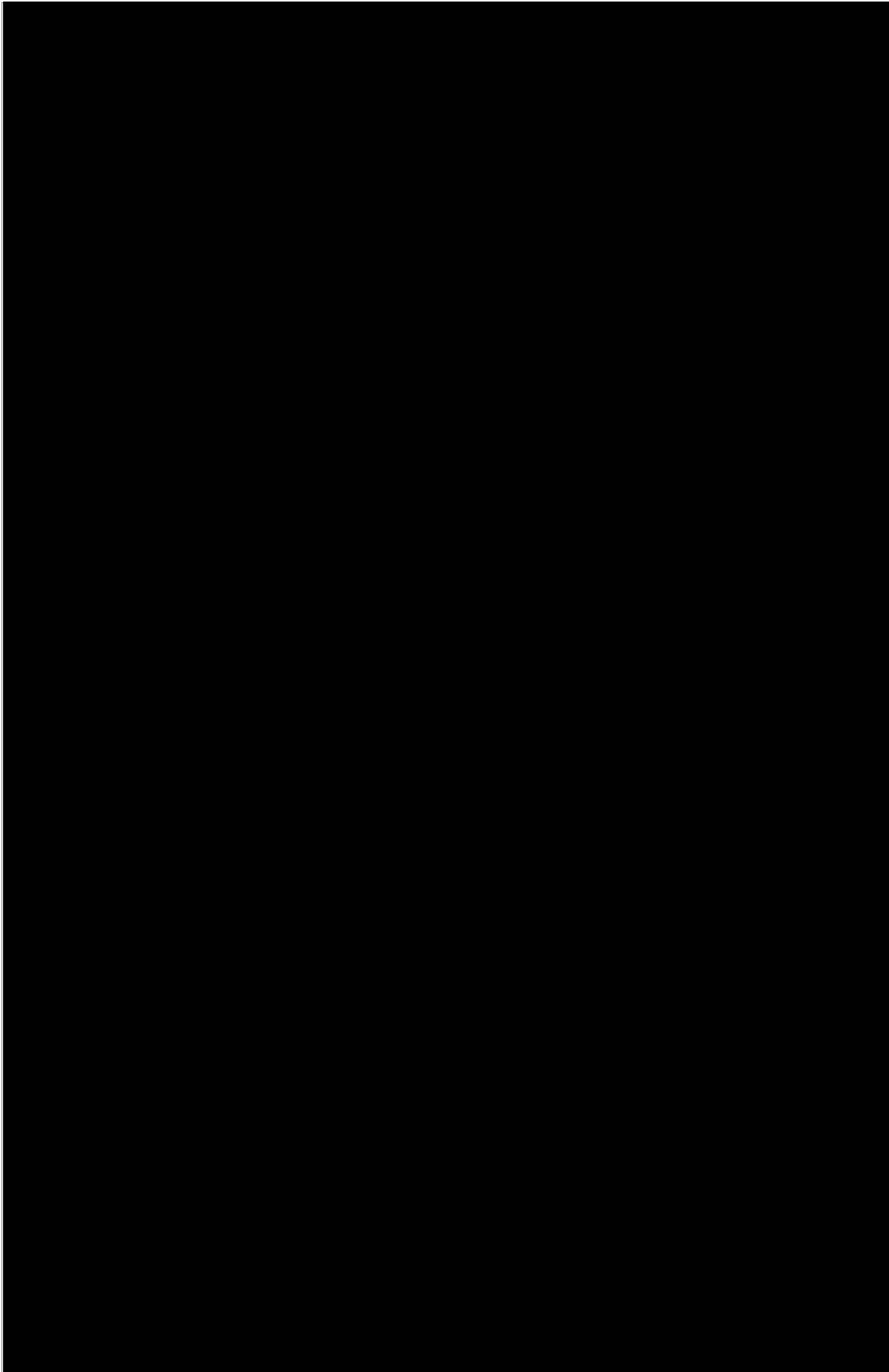


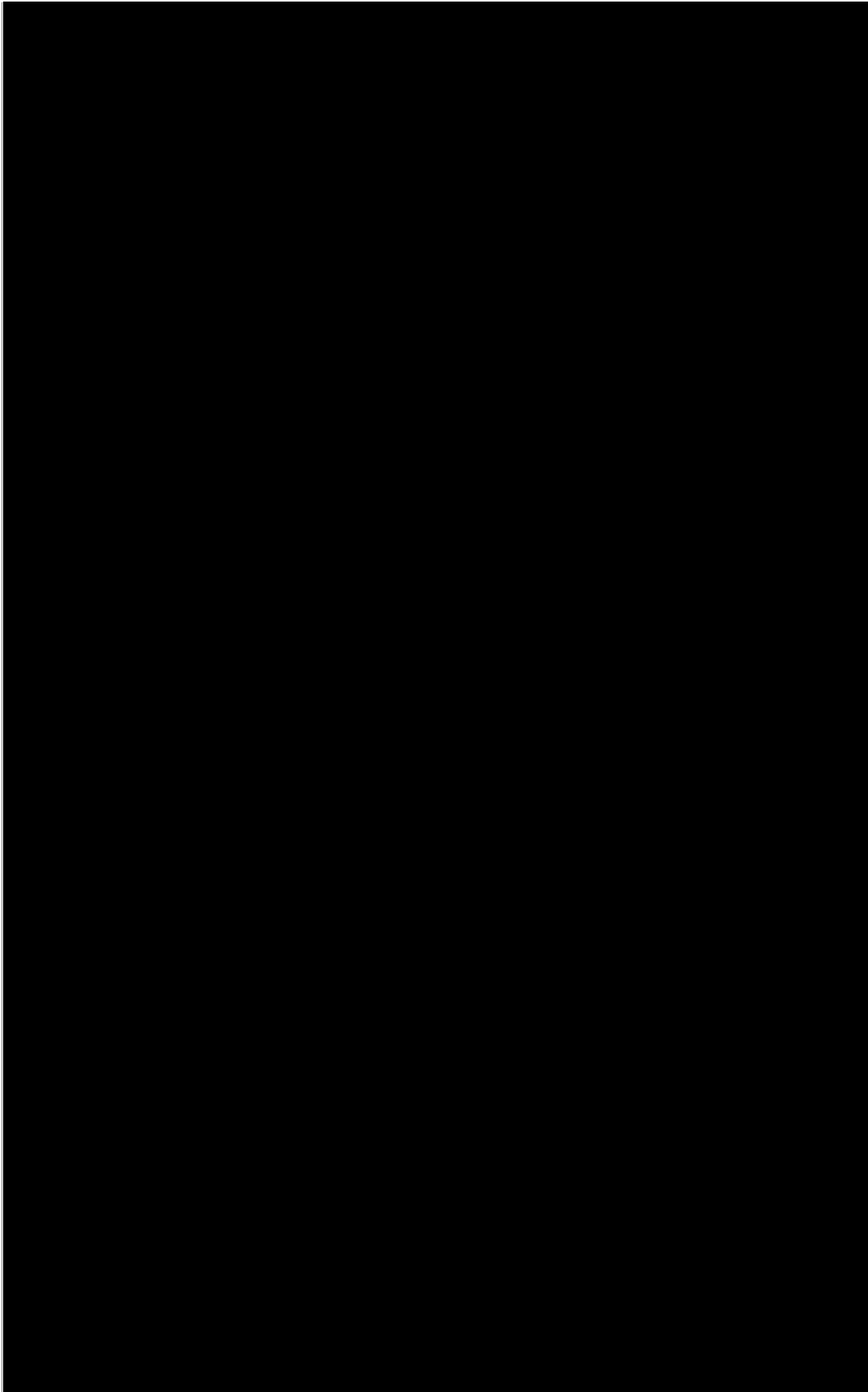




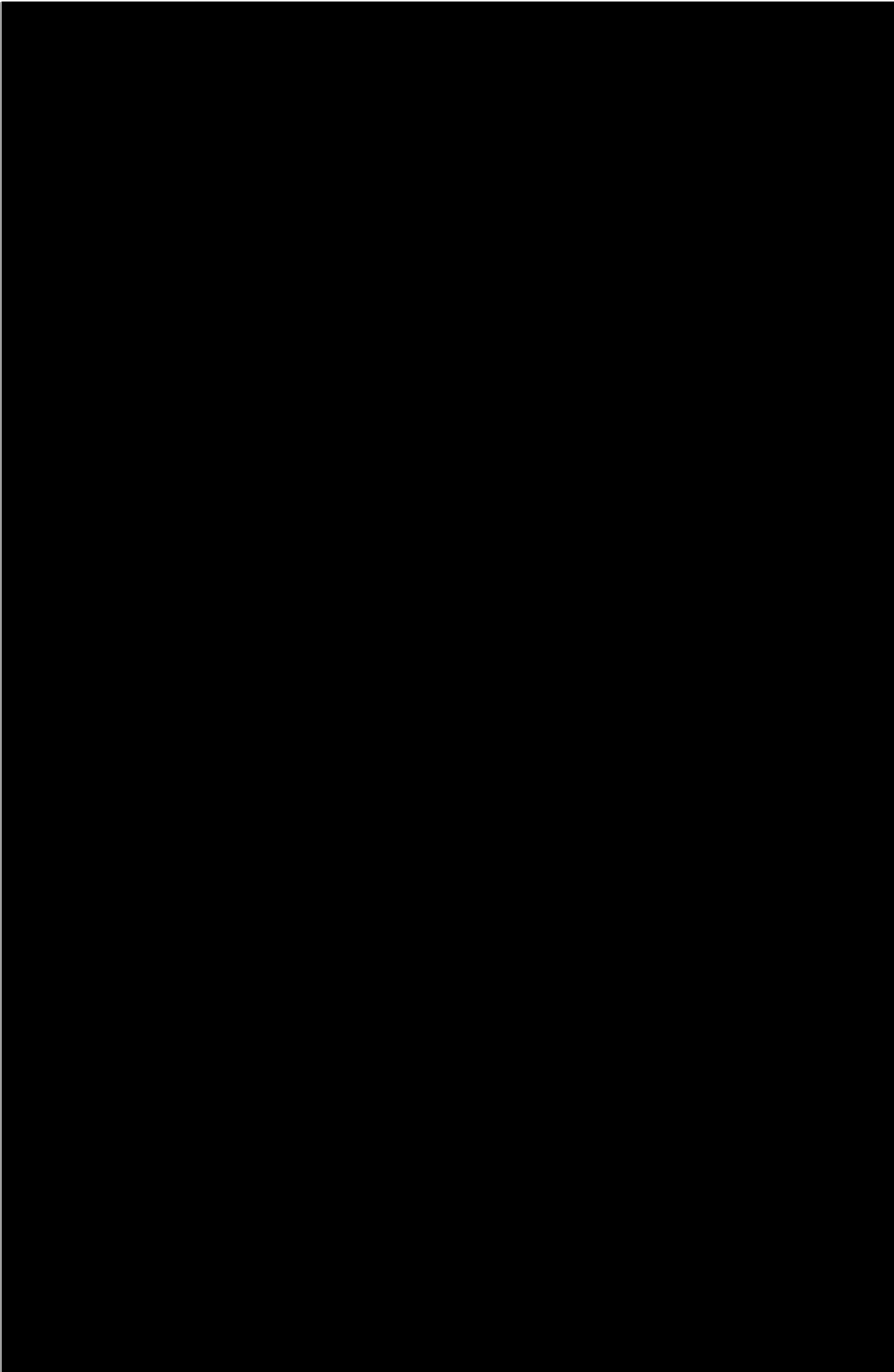


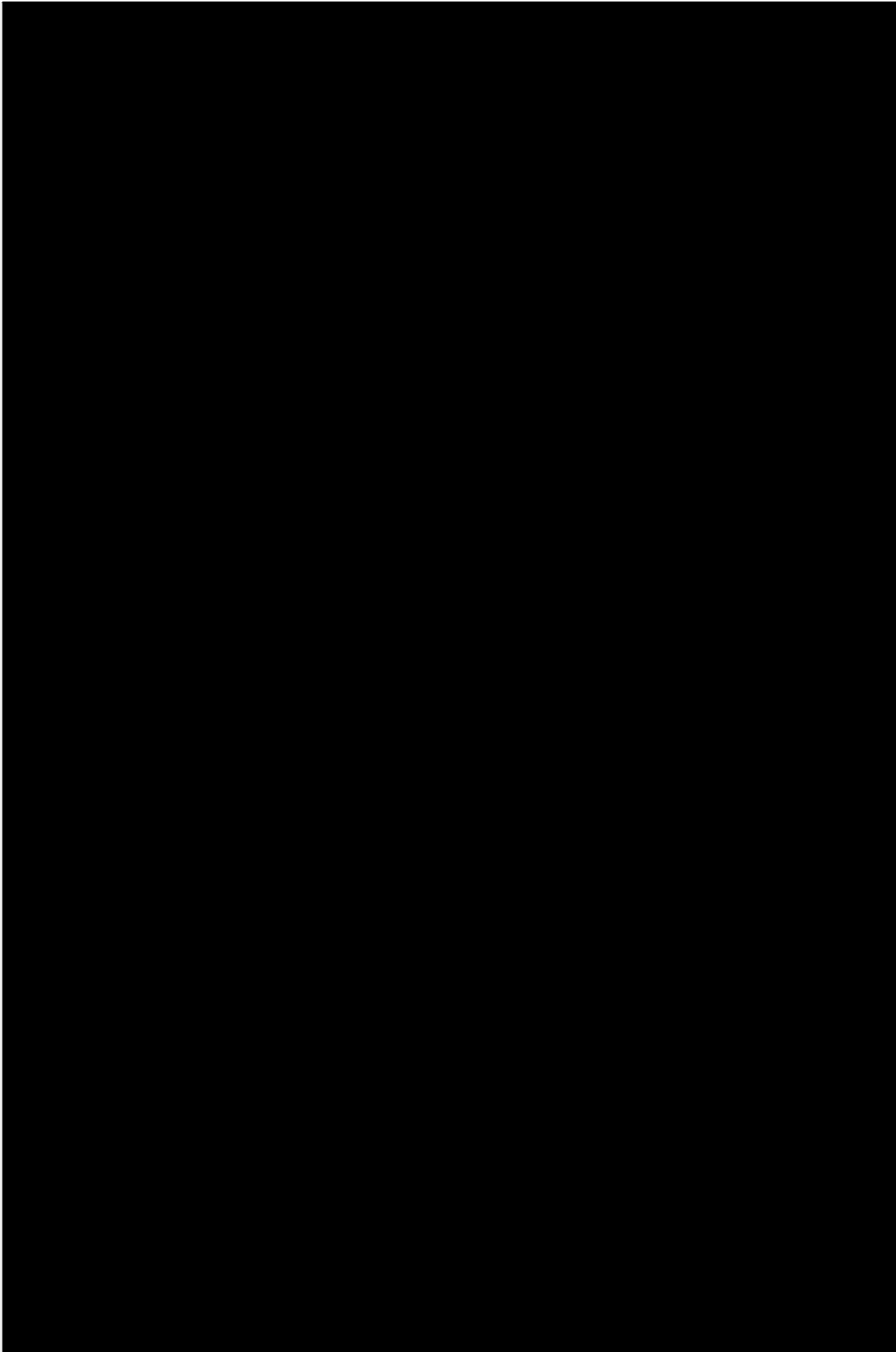


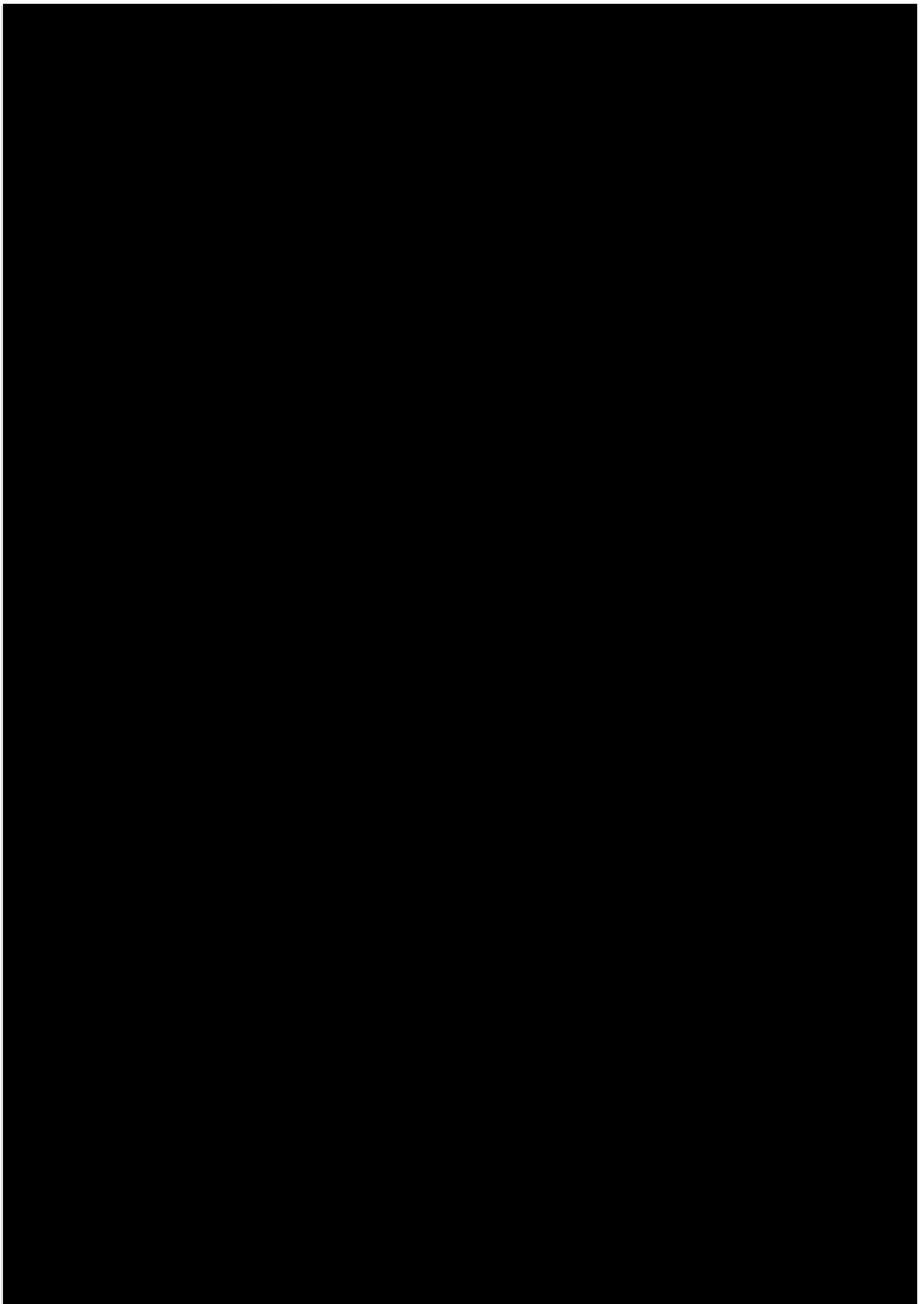


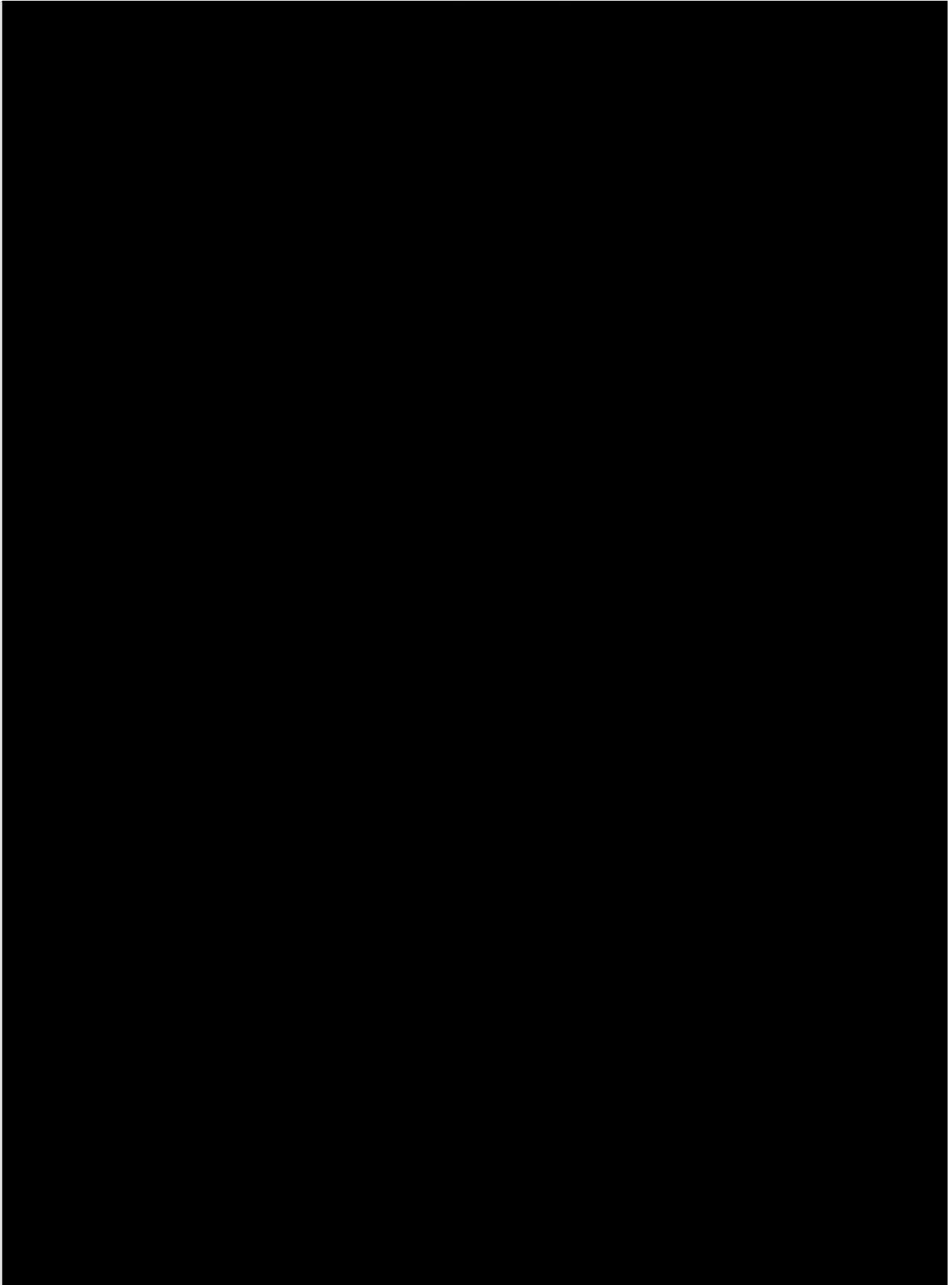


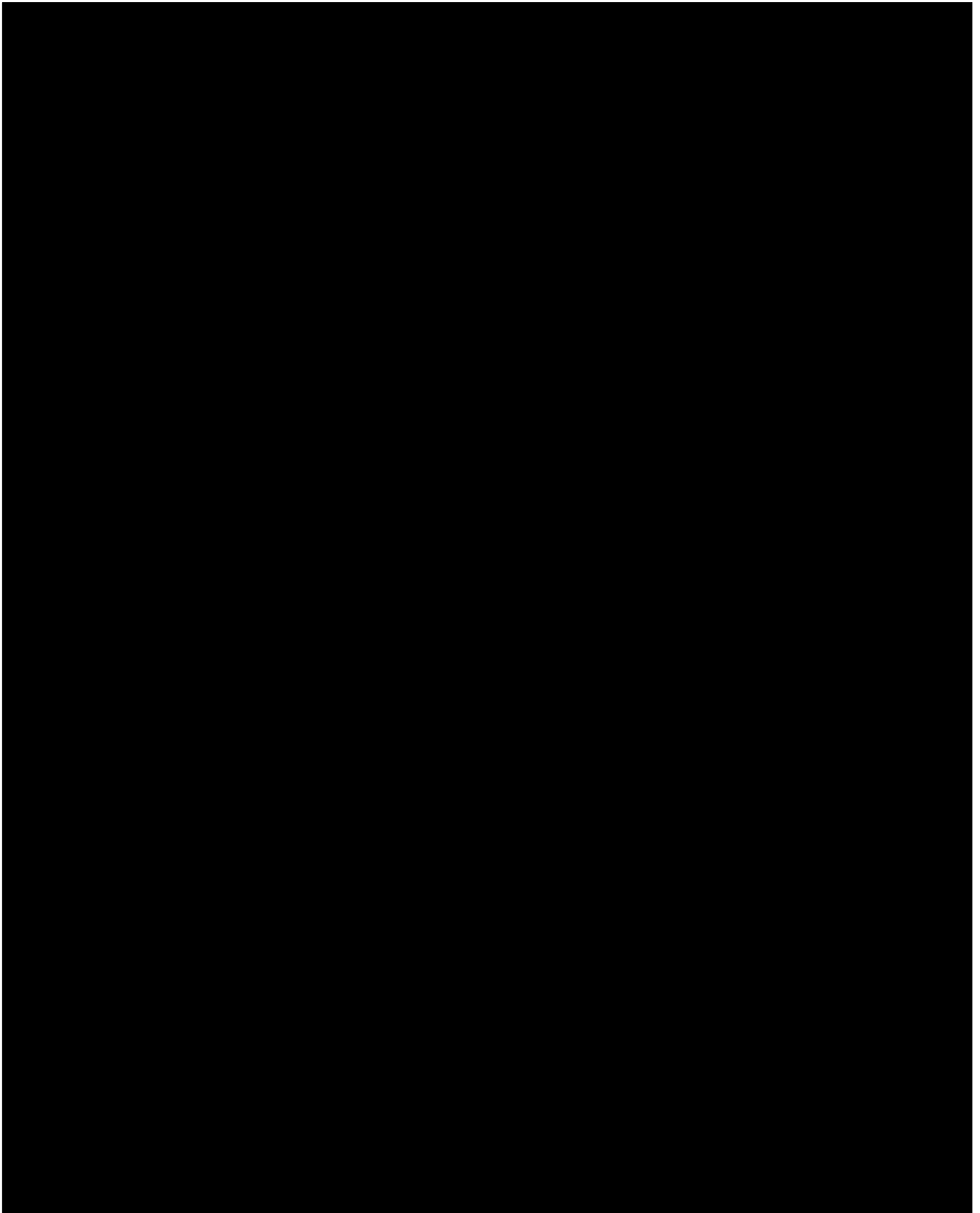


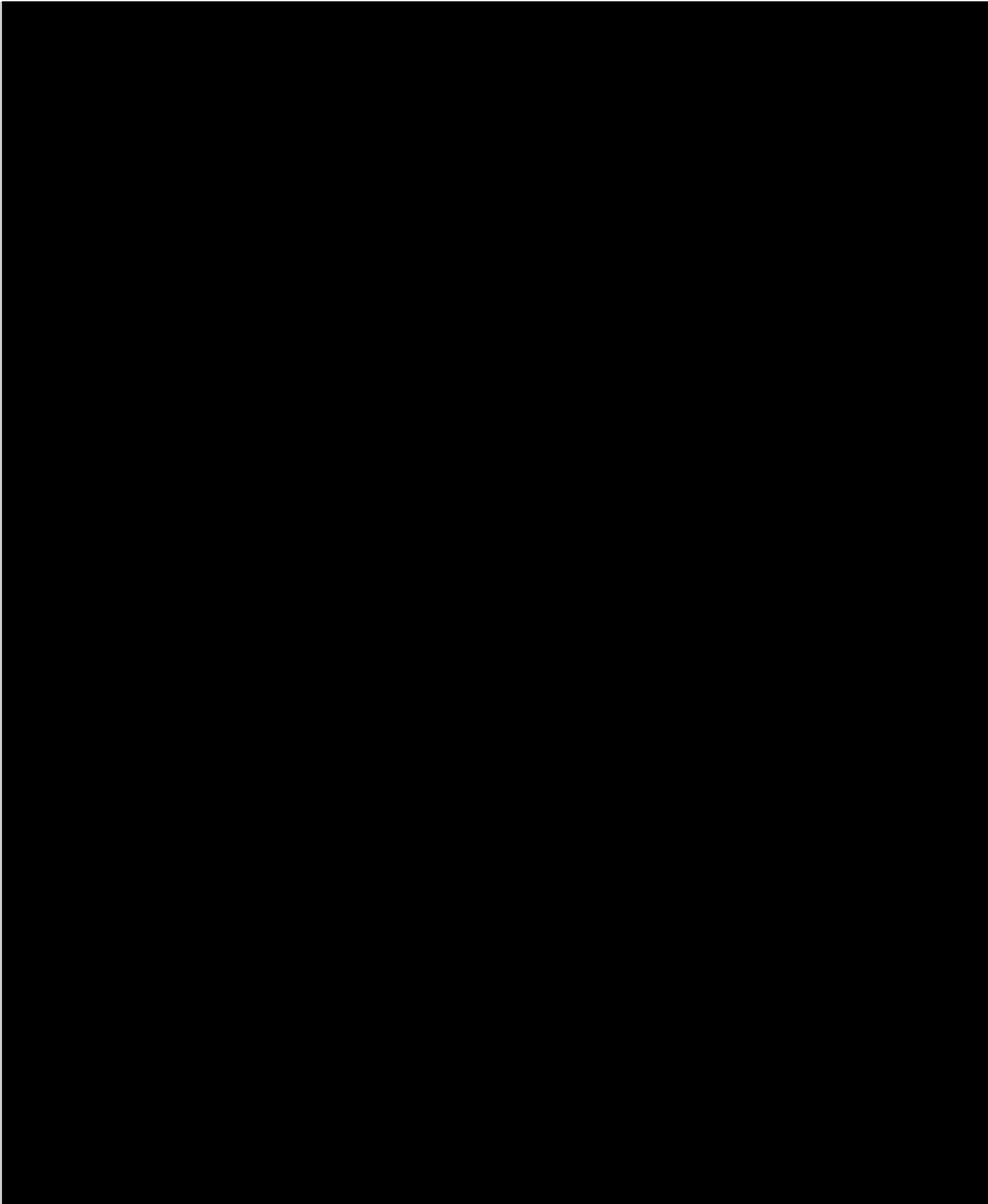


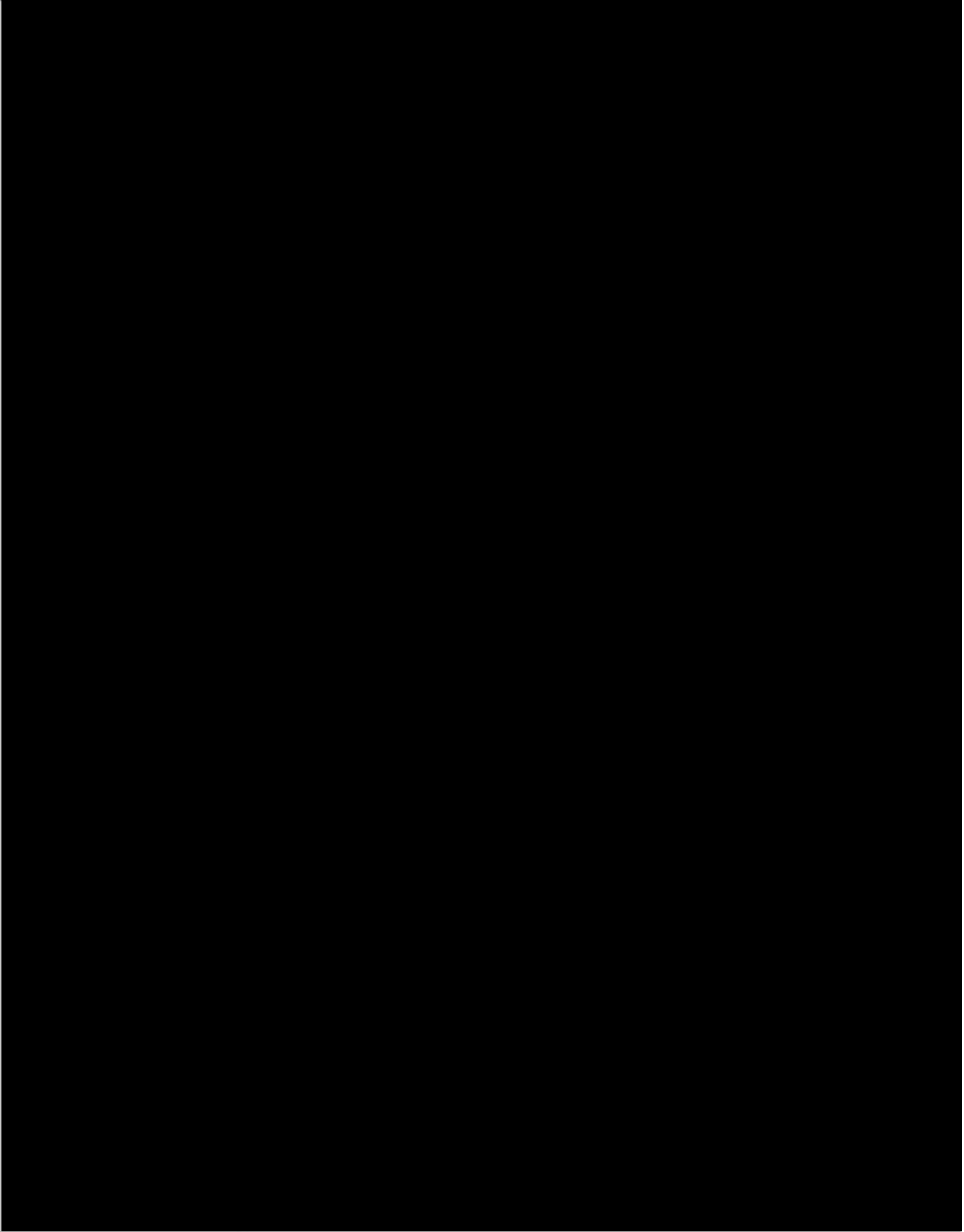


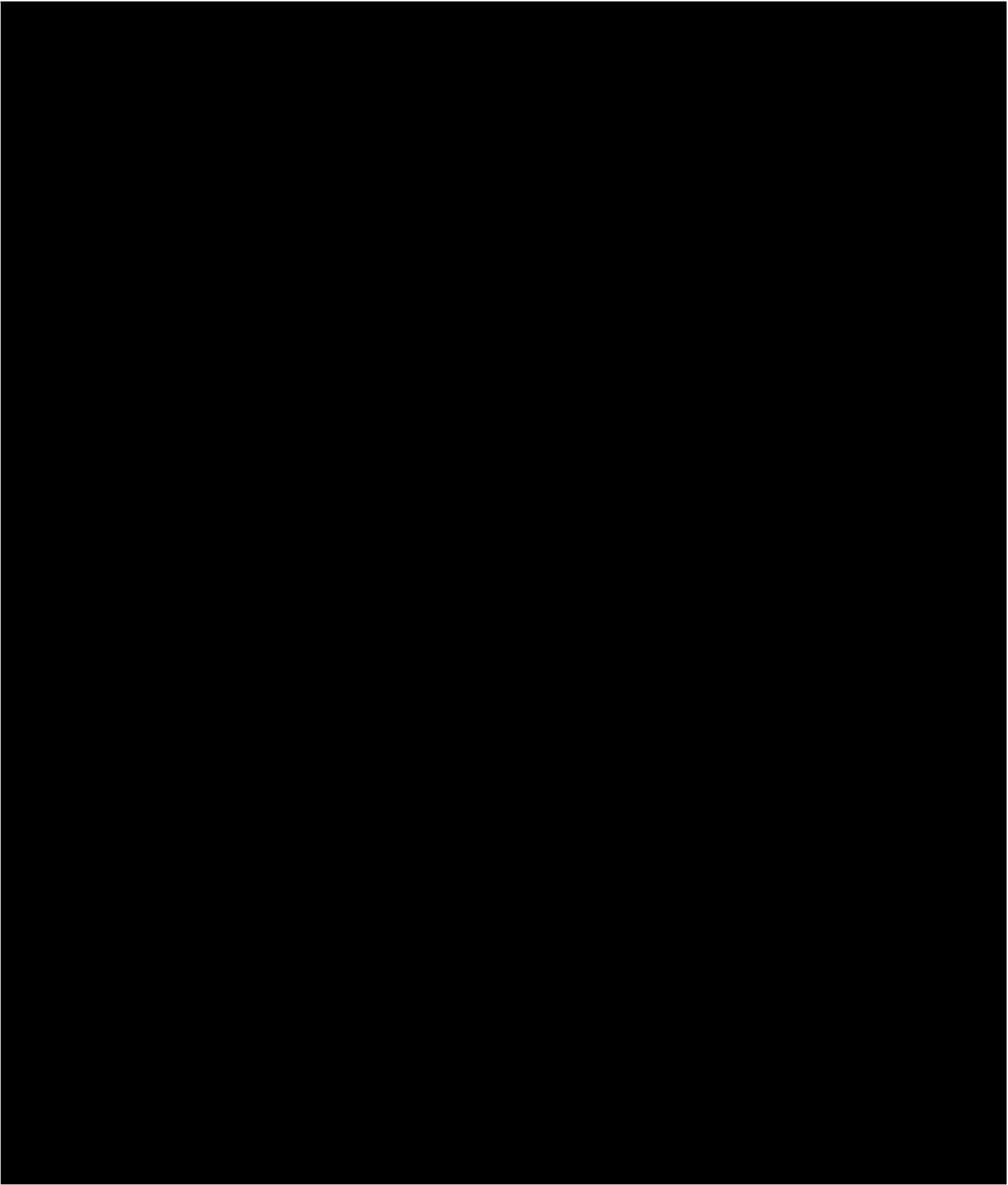








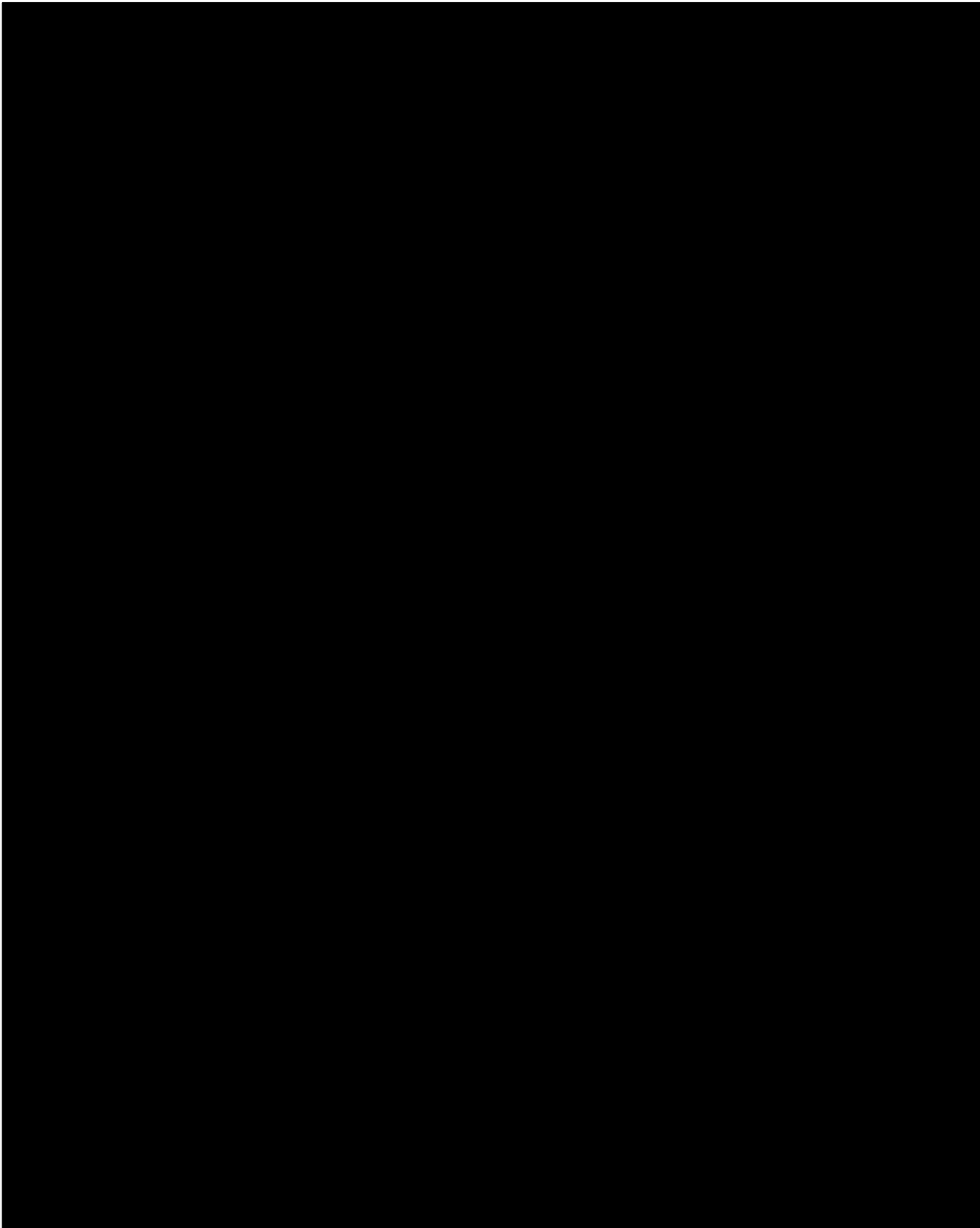




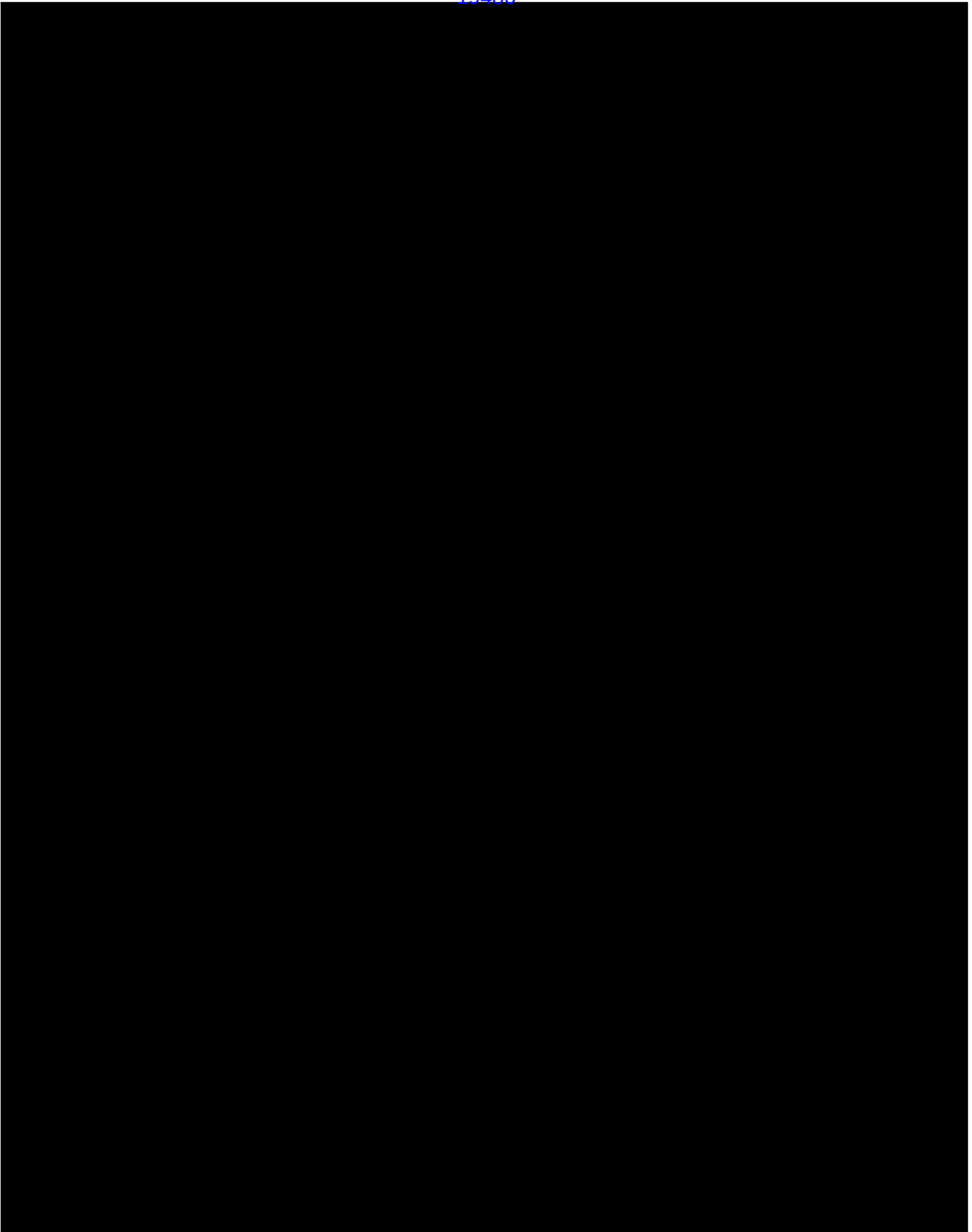




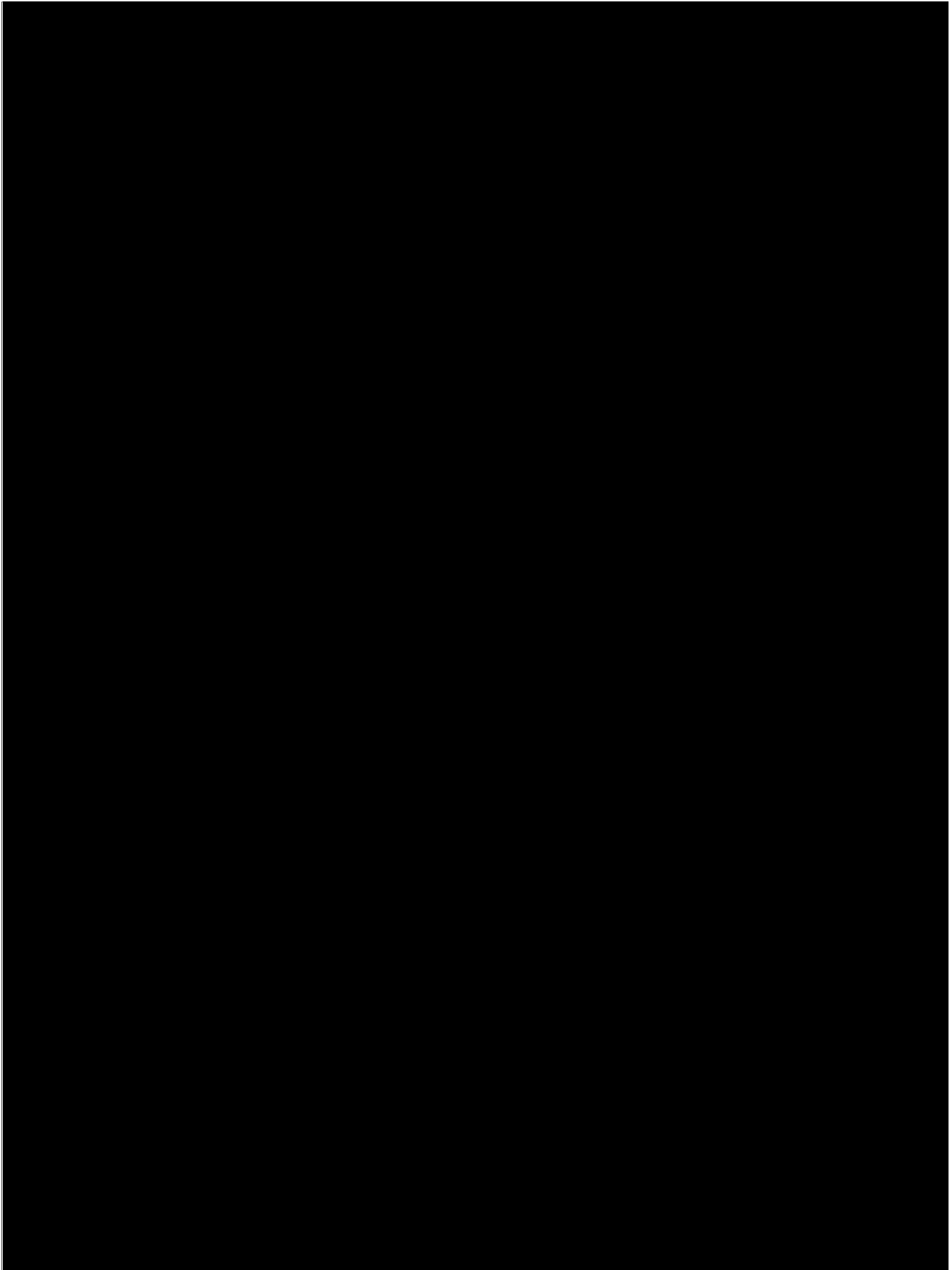


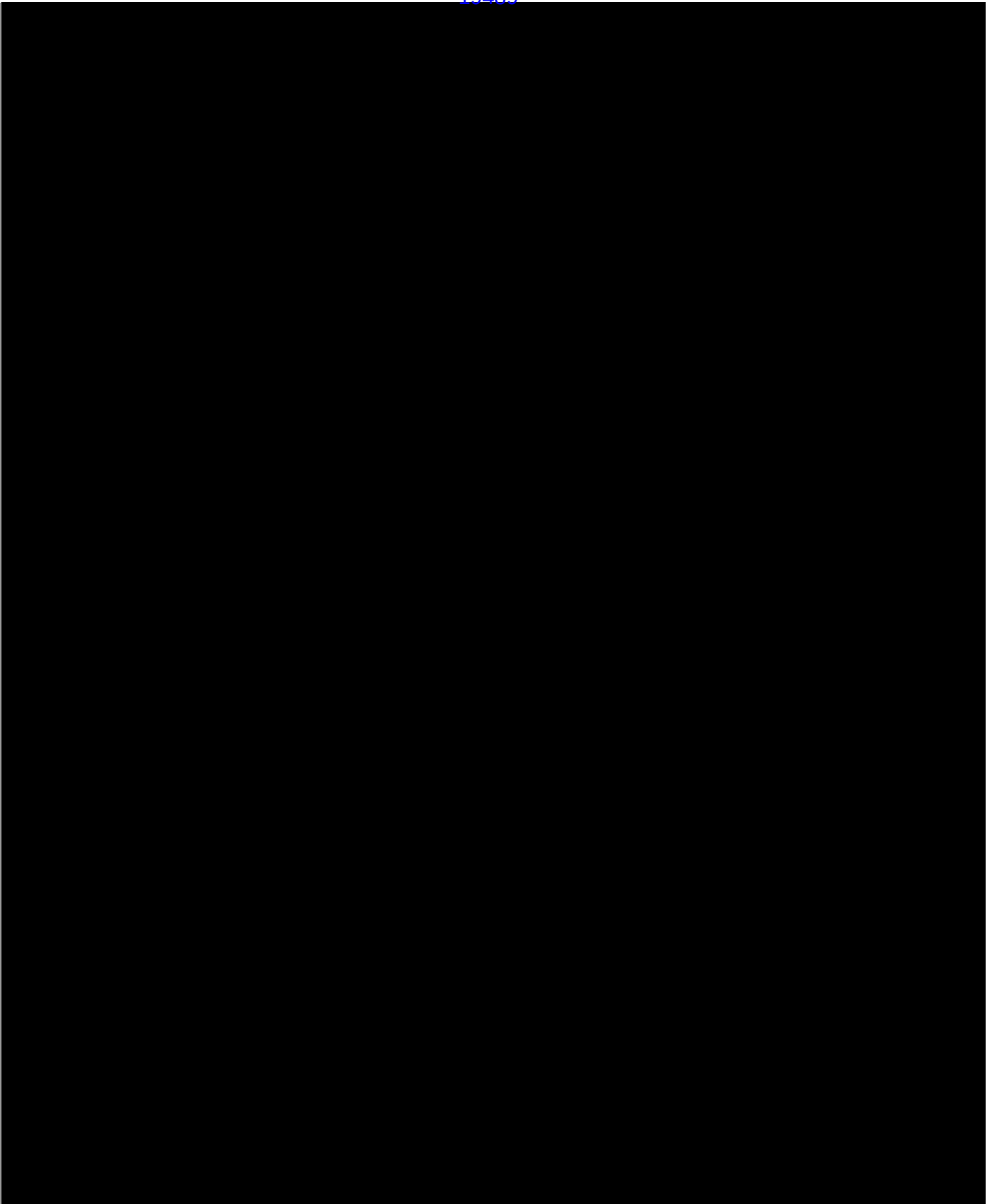




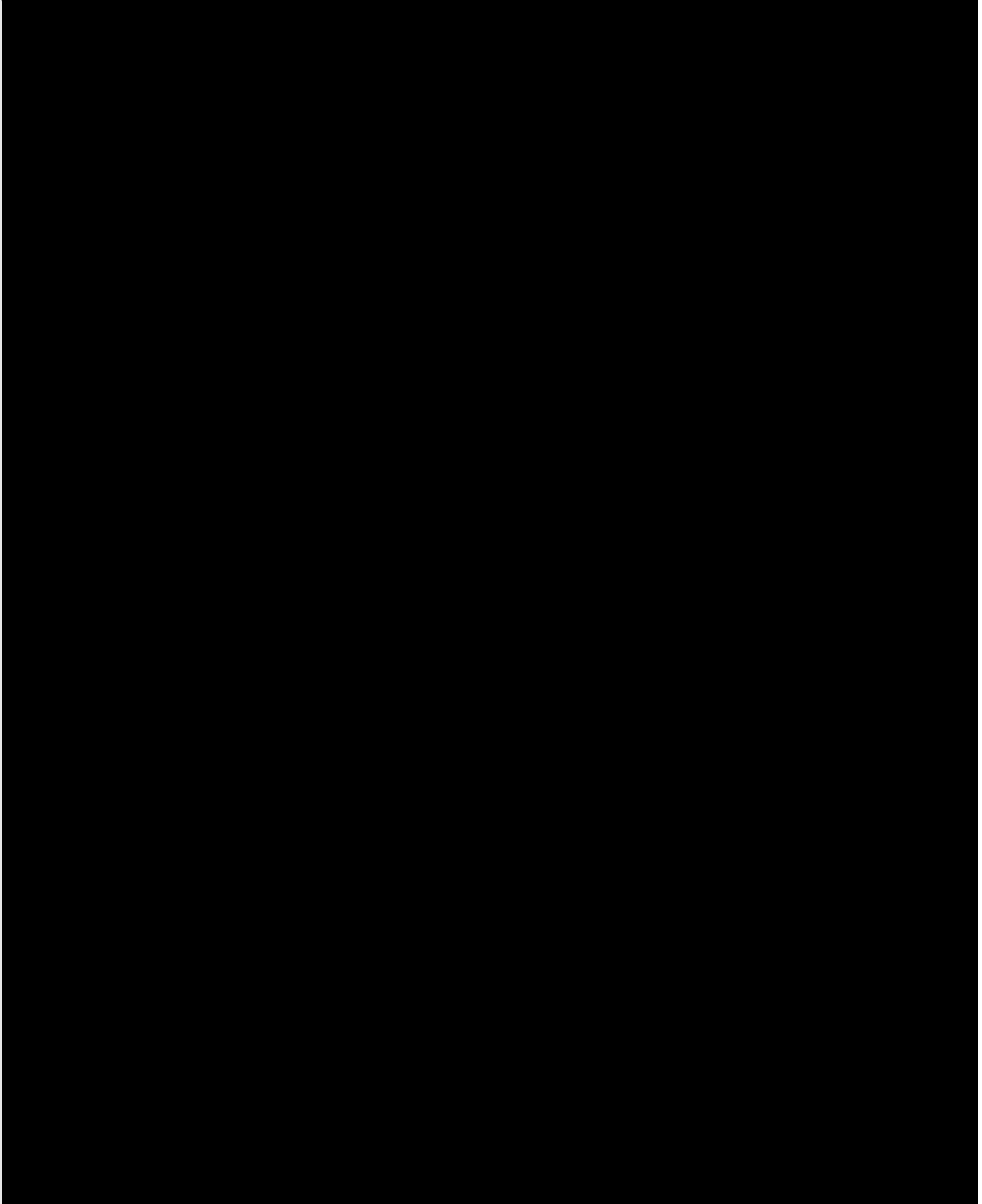


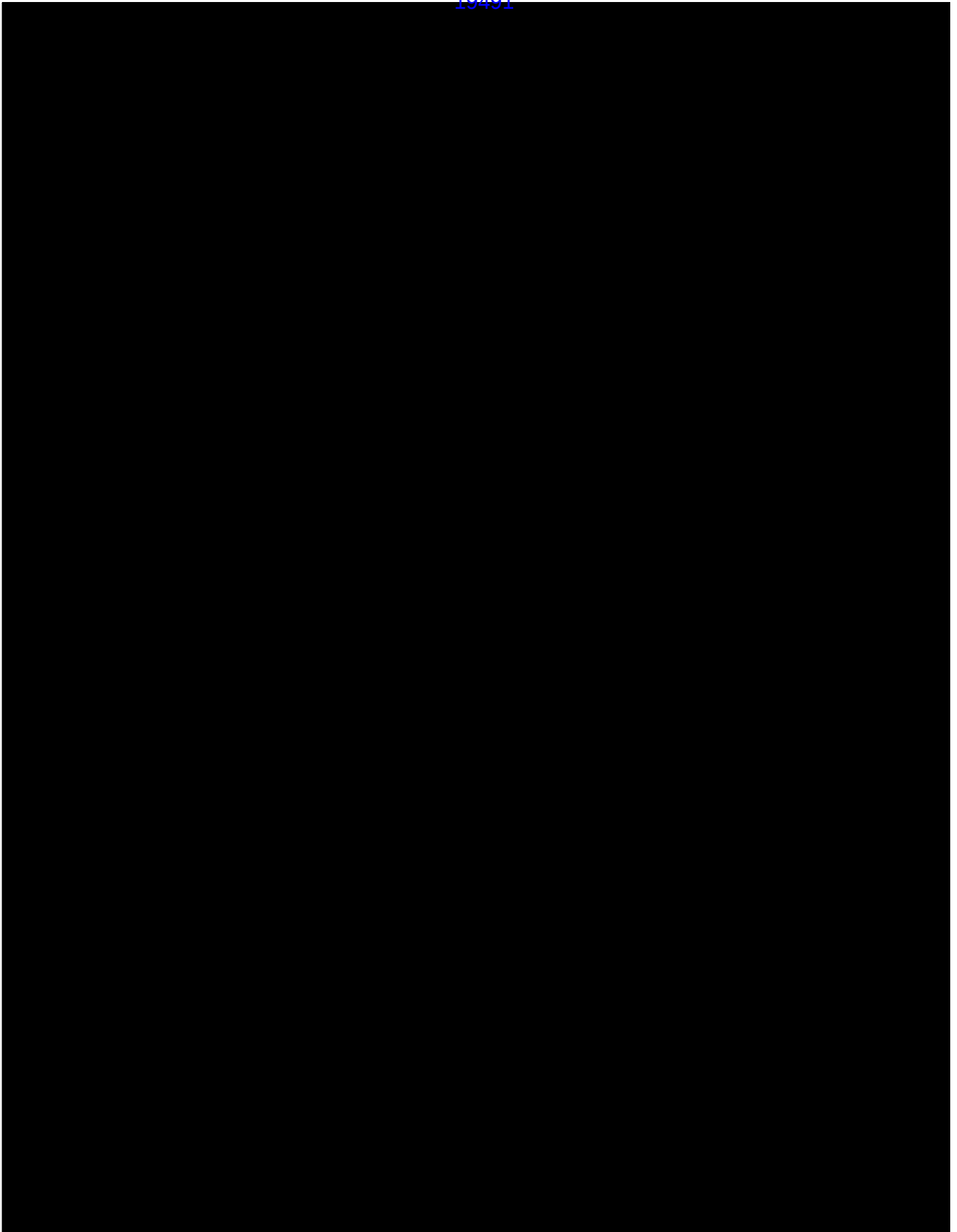




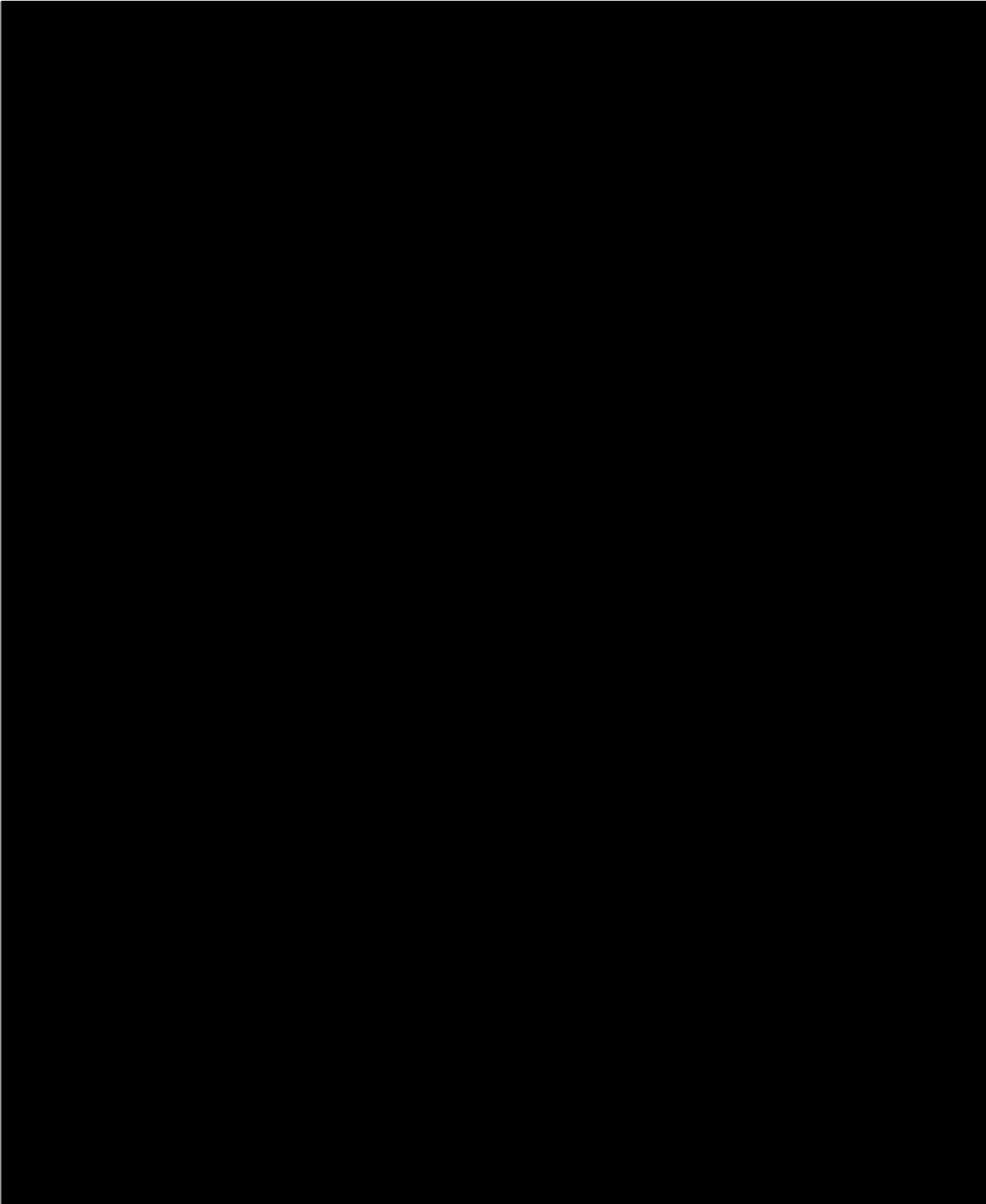




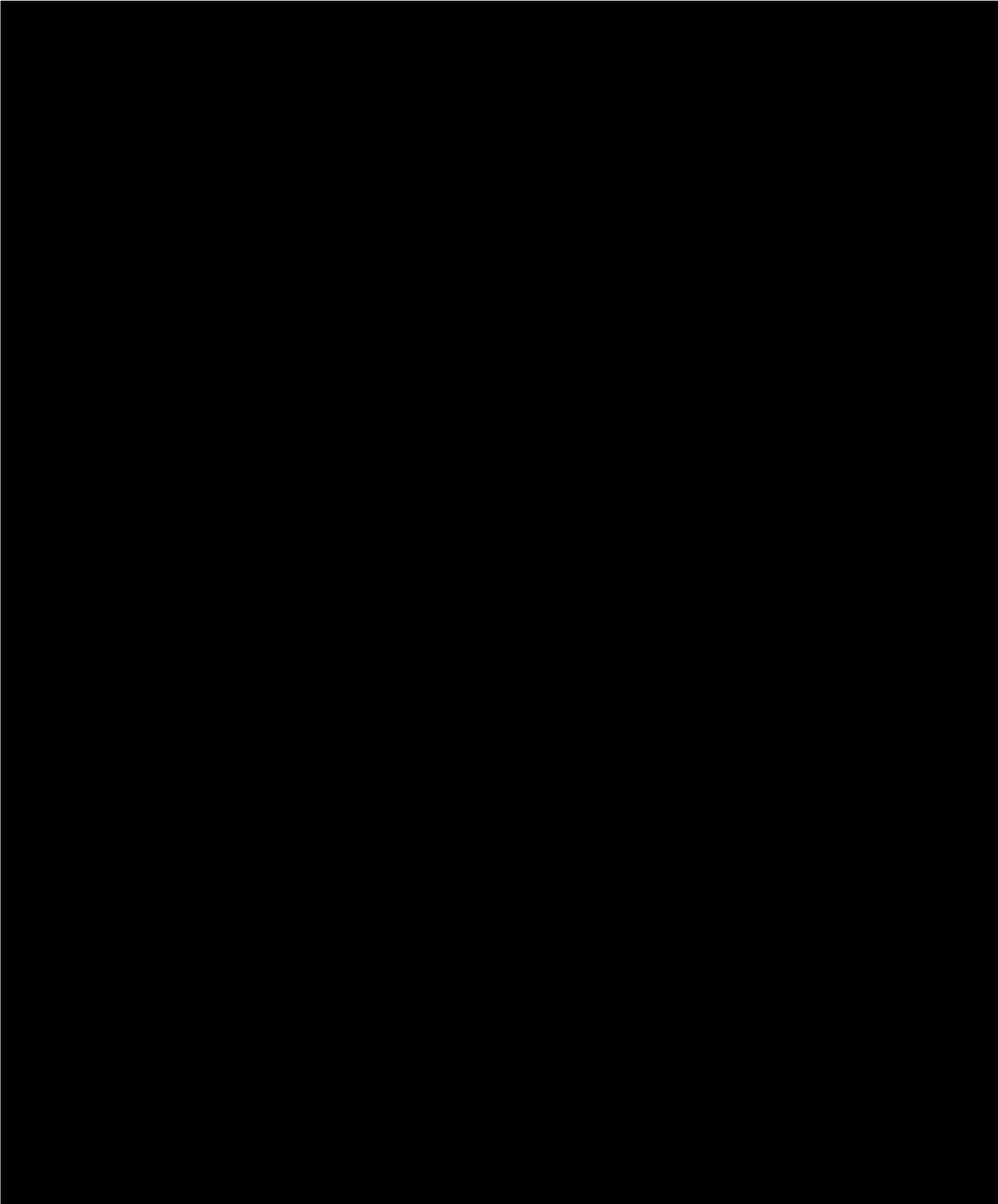




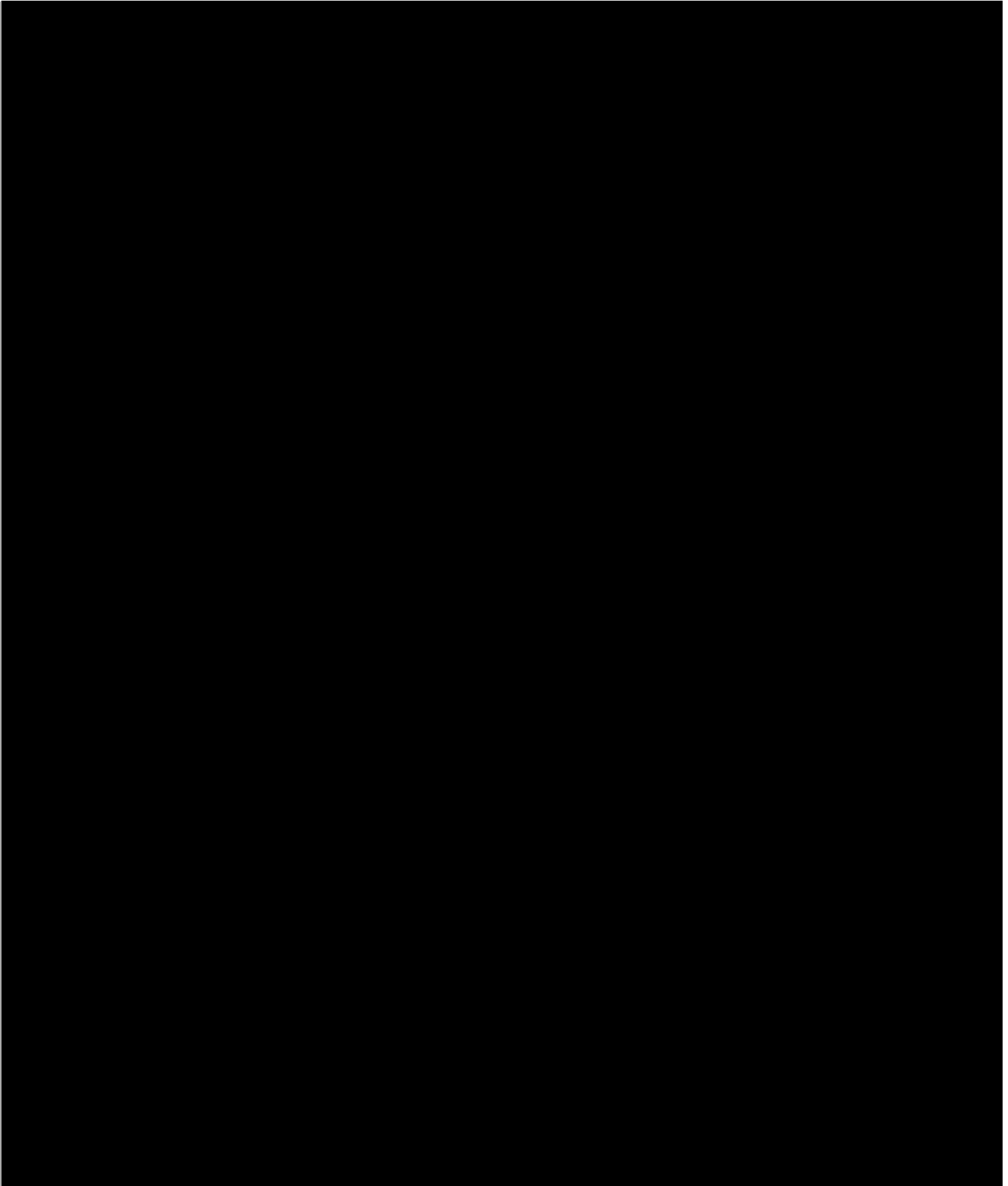








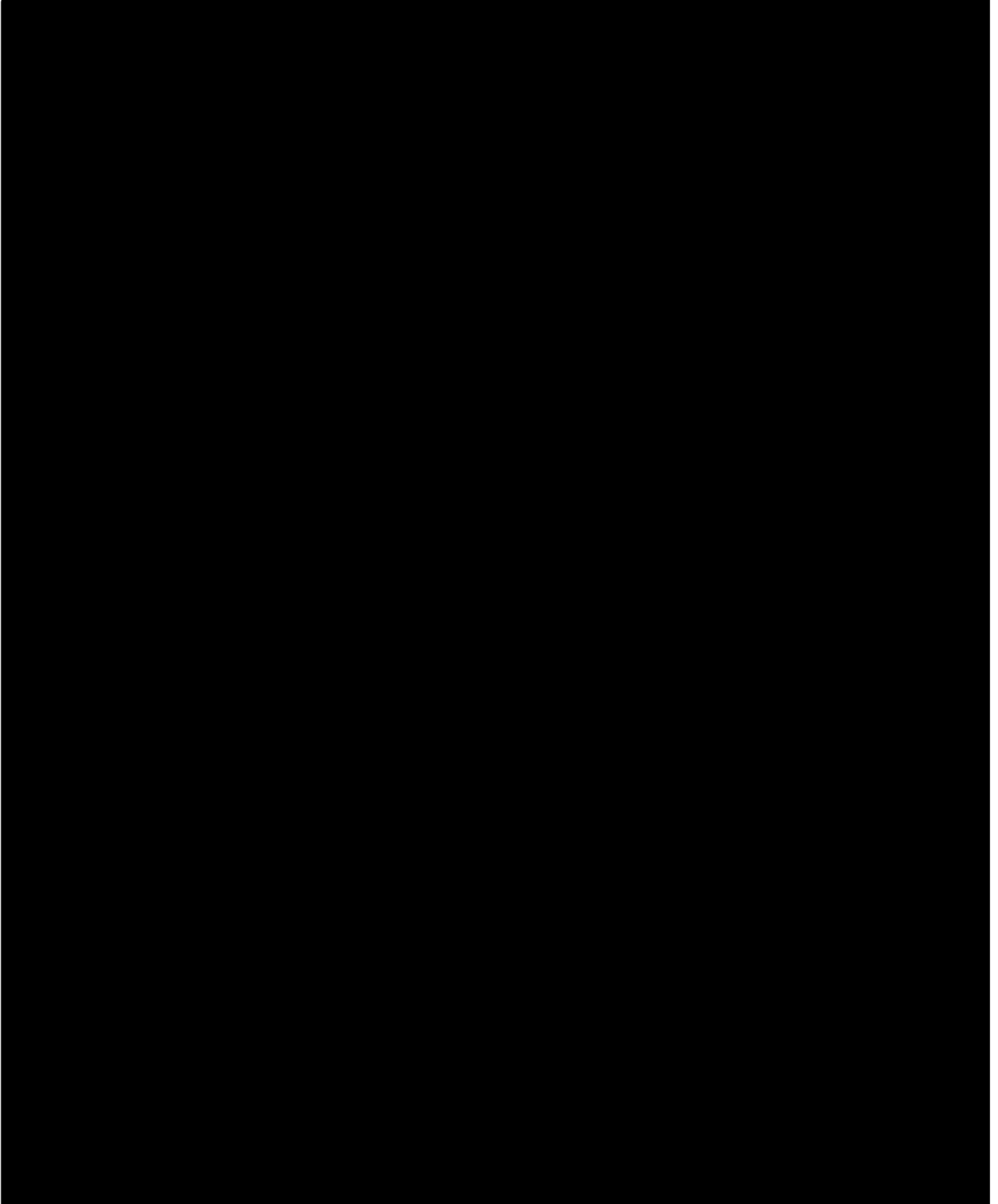


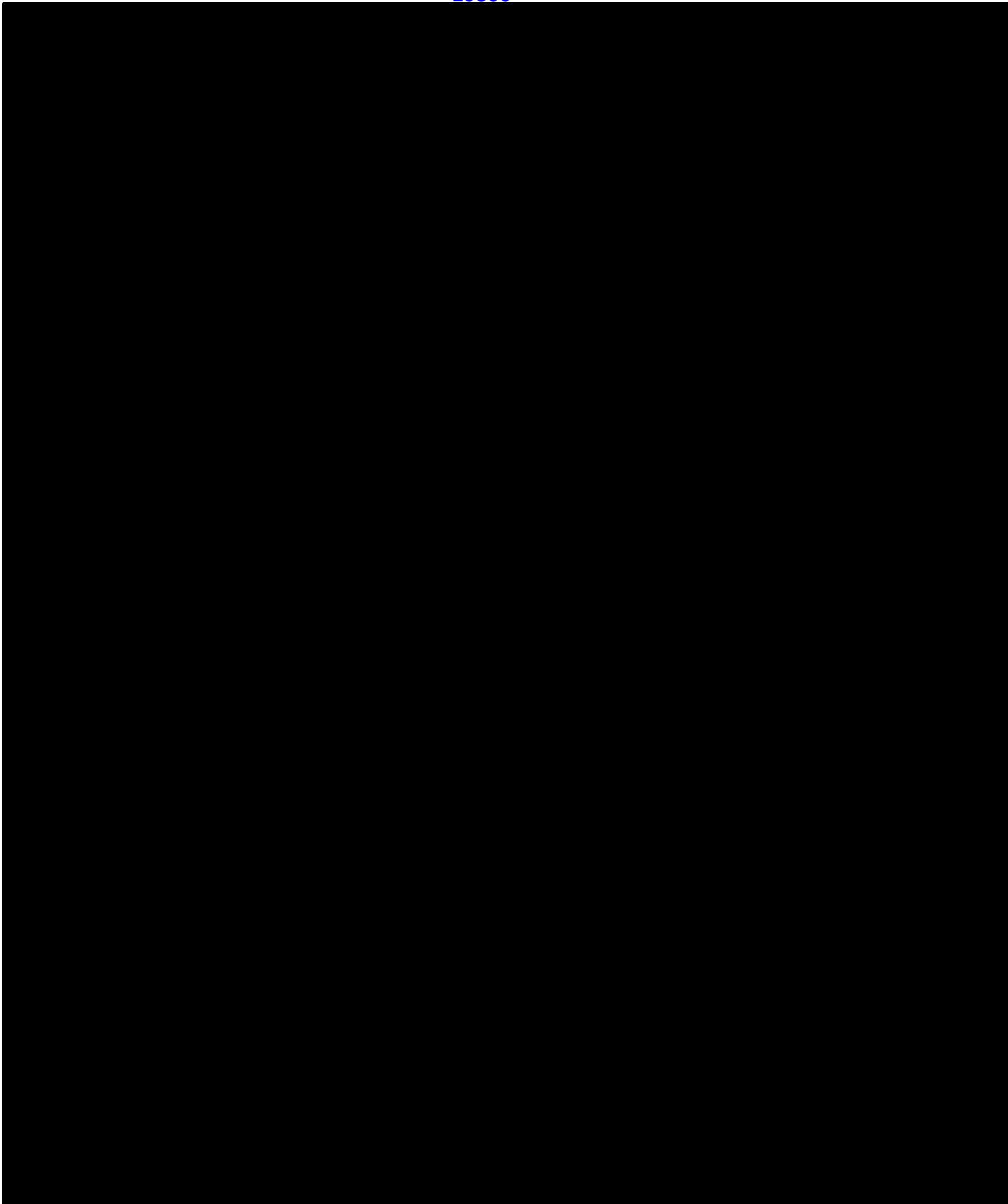


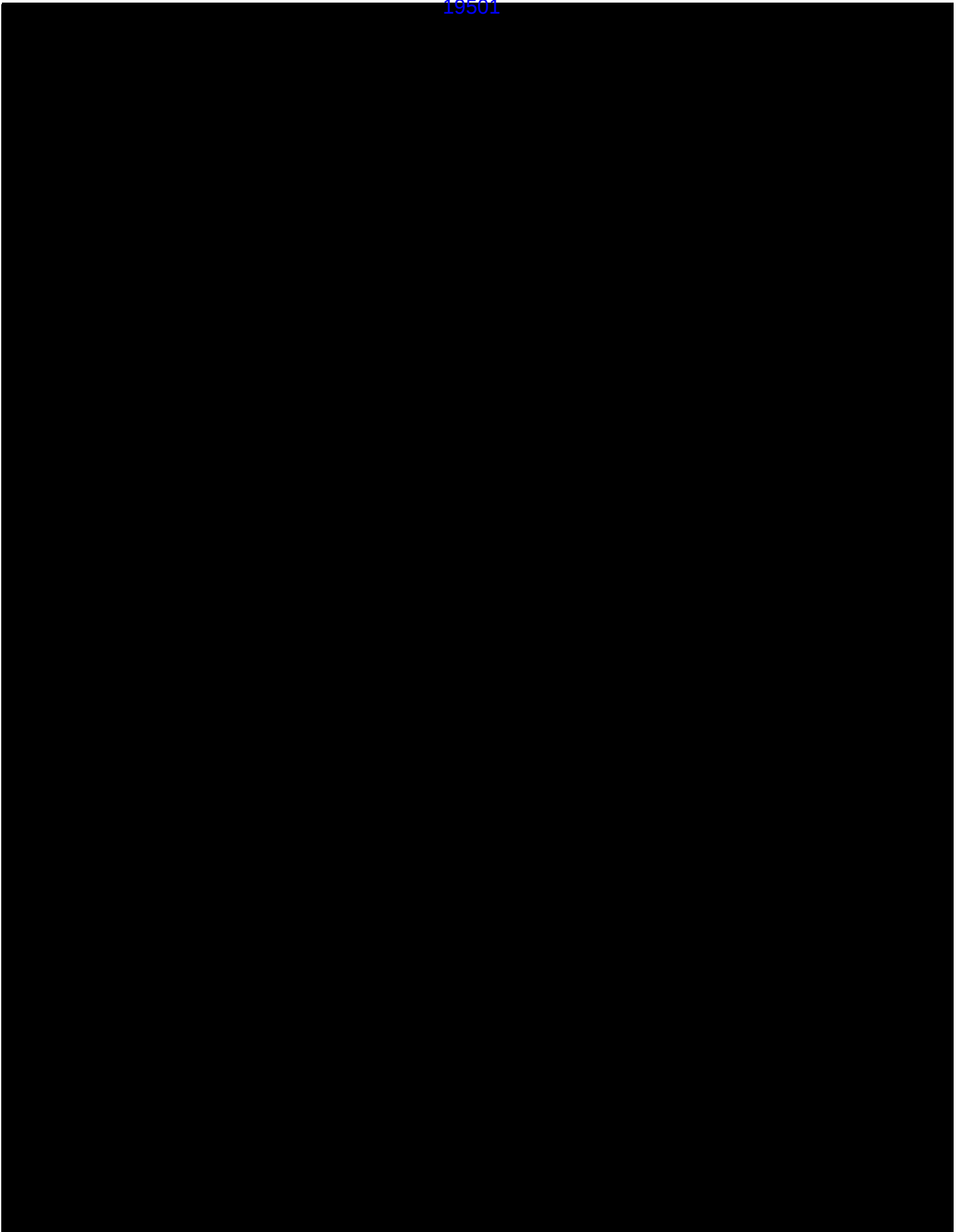


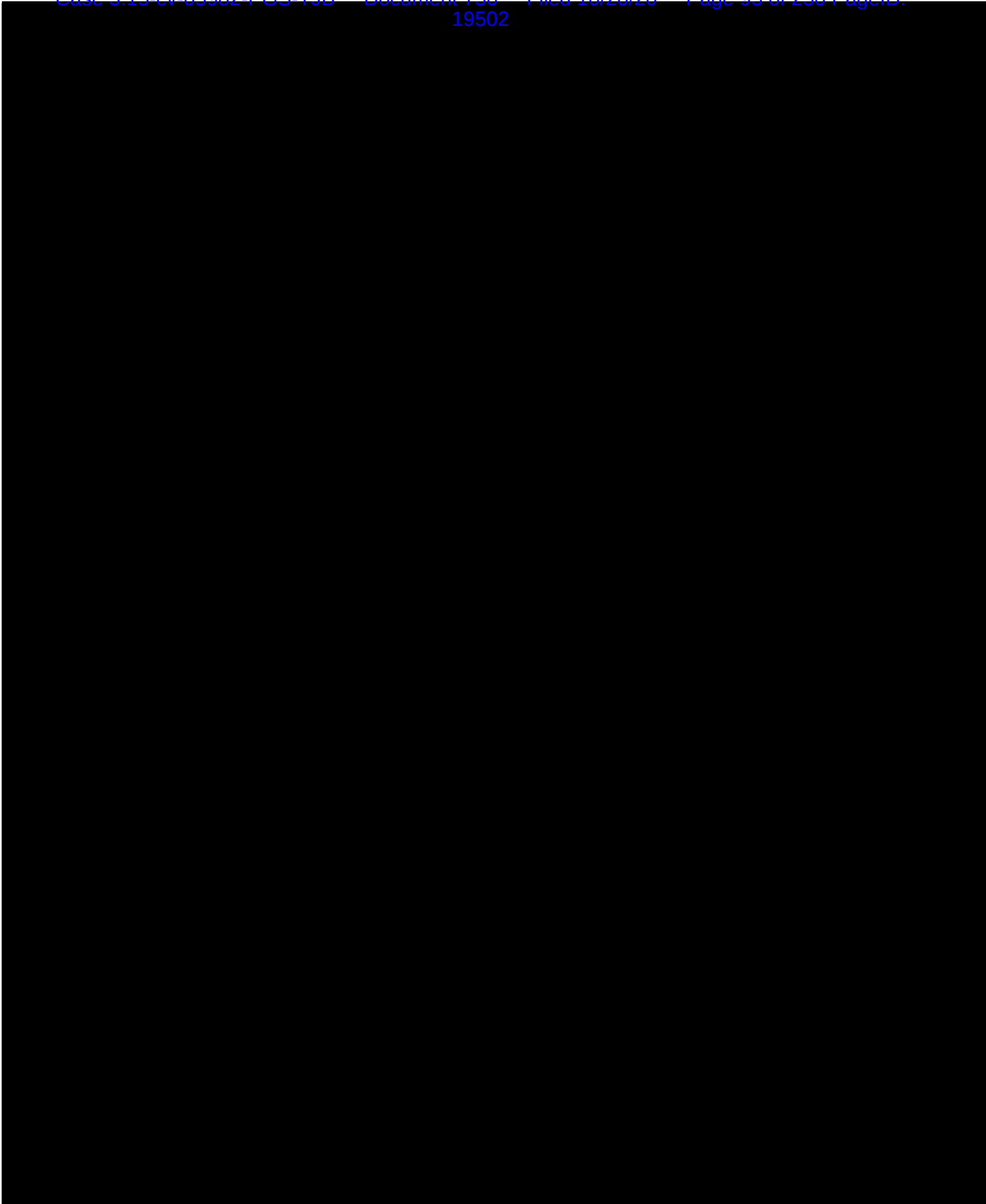
# **EXHIBIT 3**

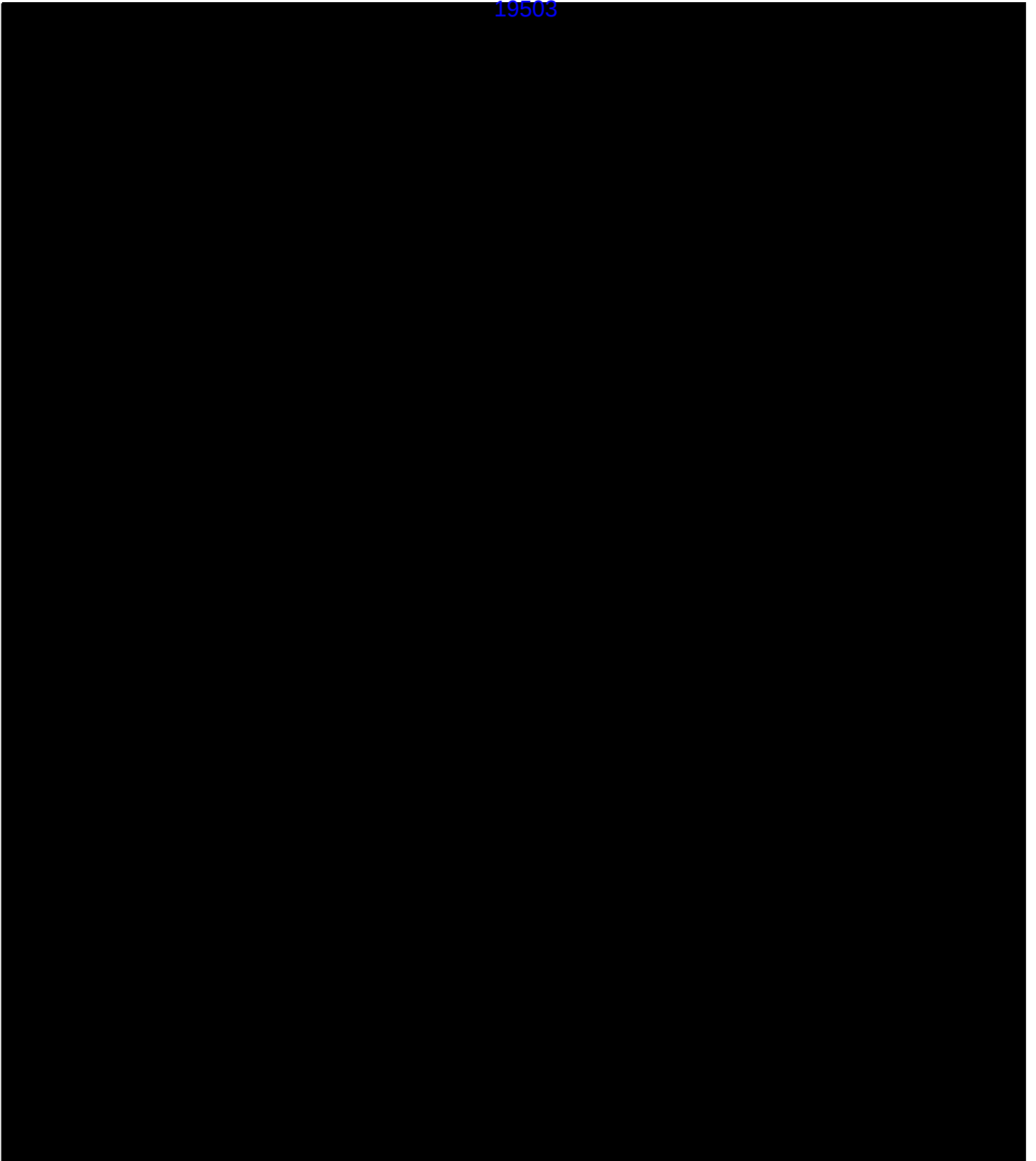
## **FILED UNDER SEAL**

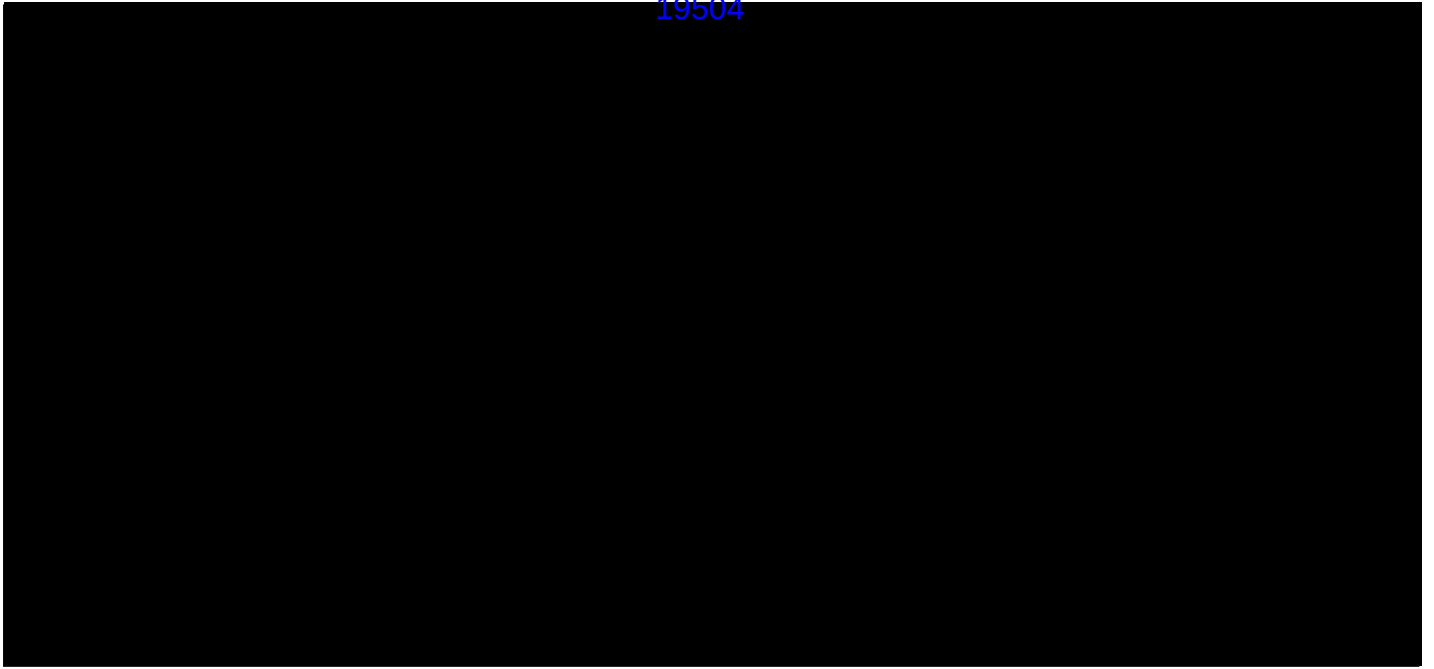


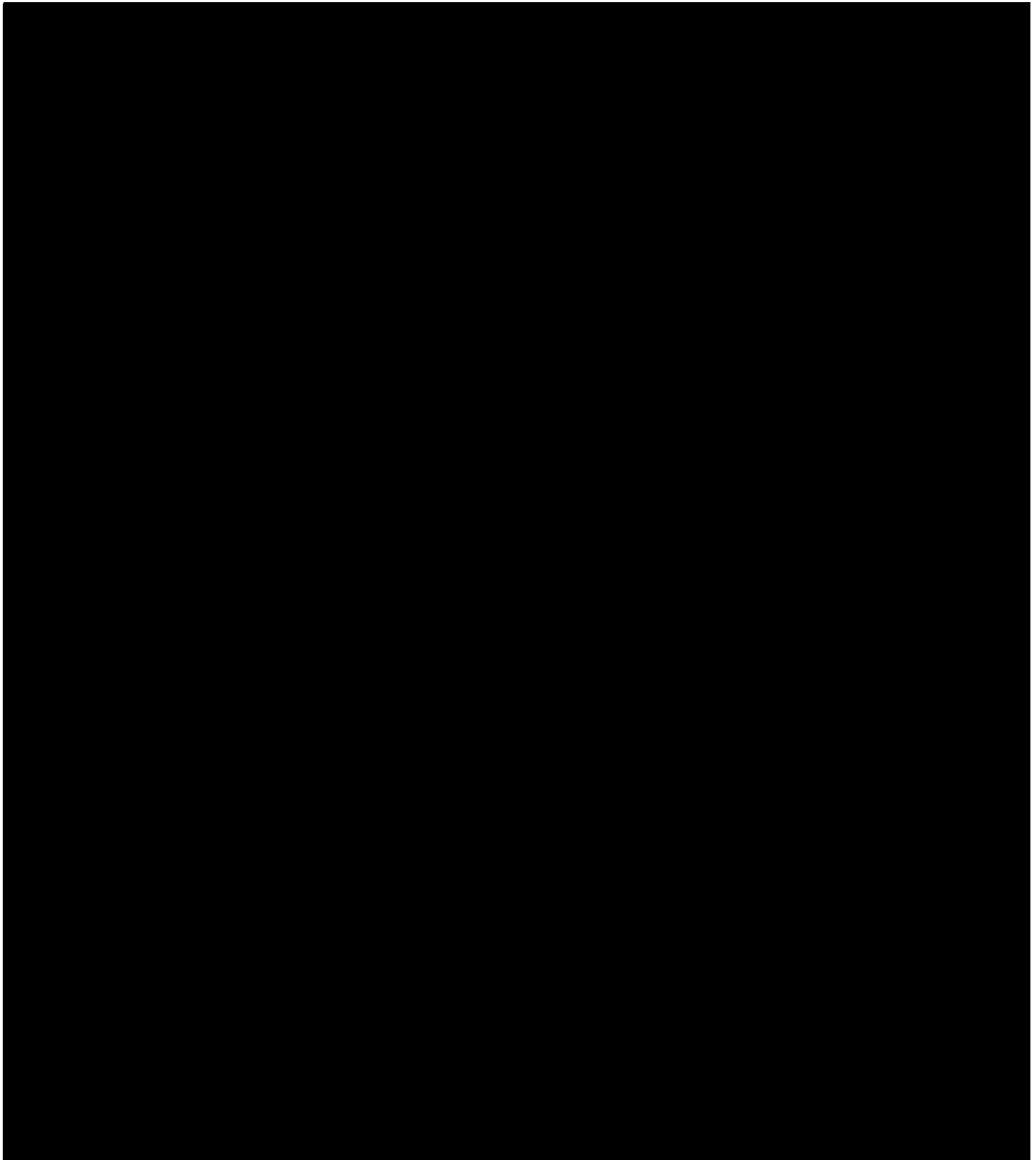




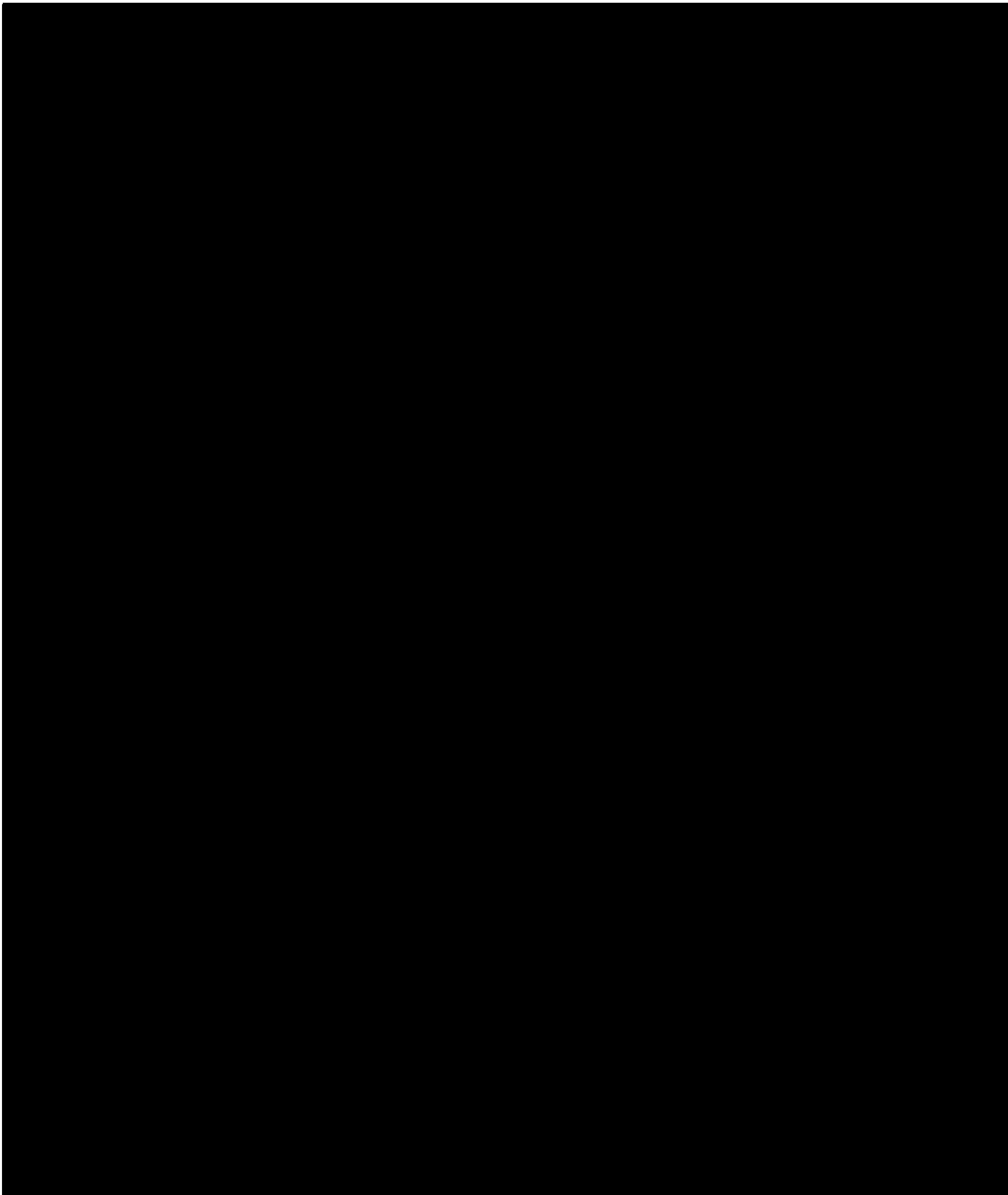


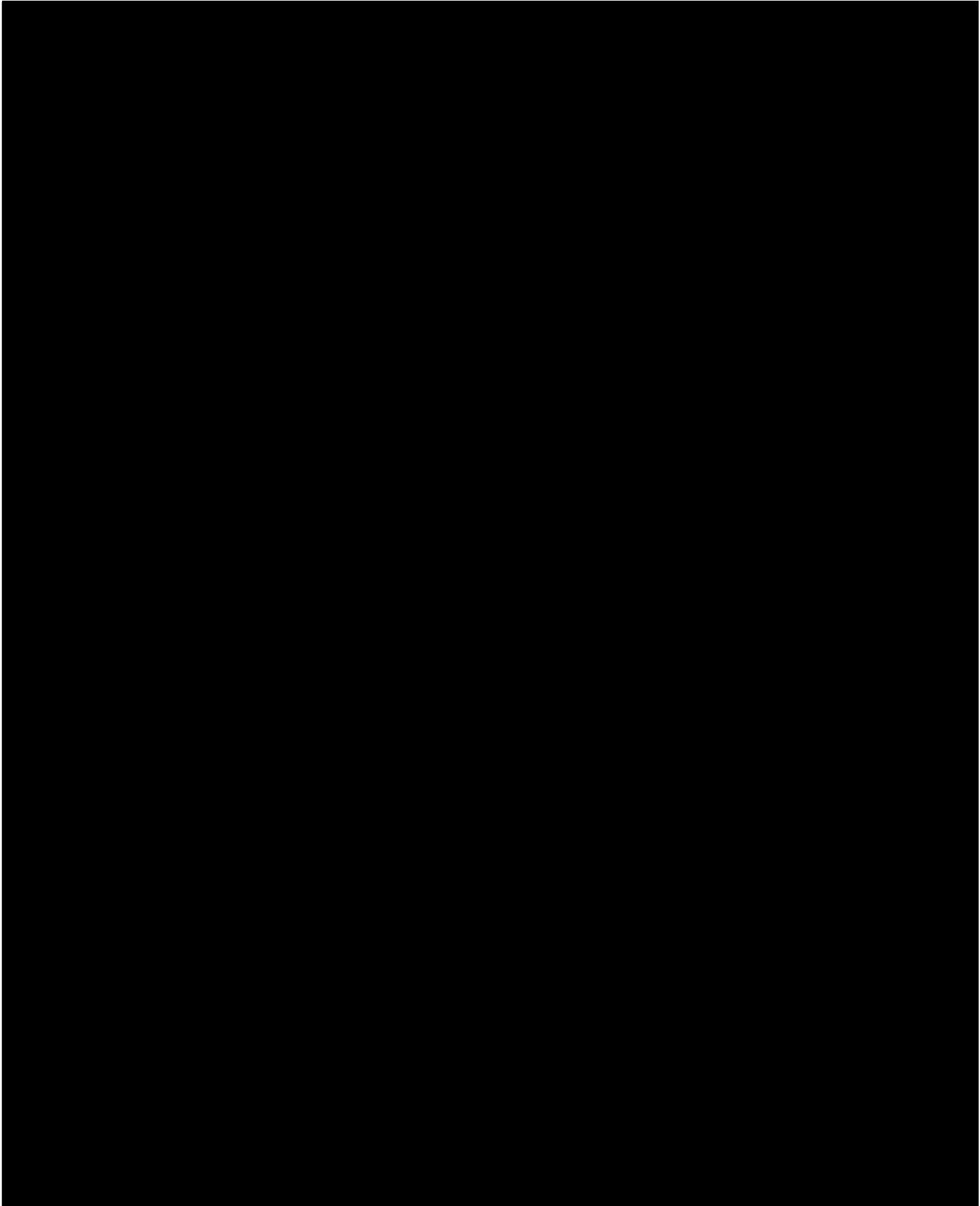


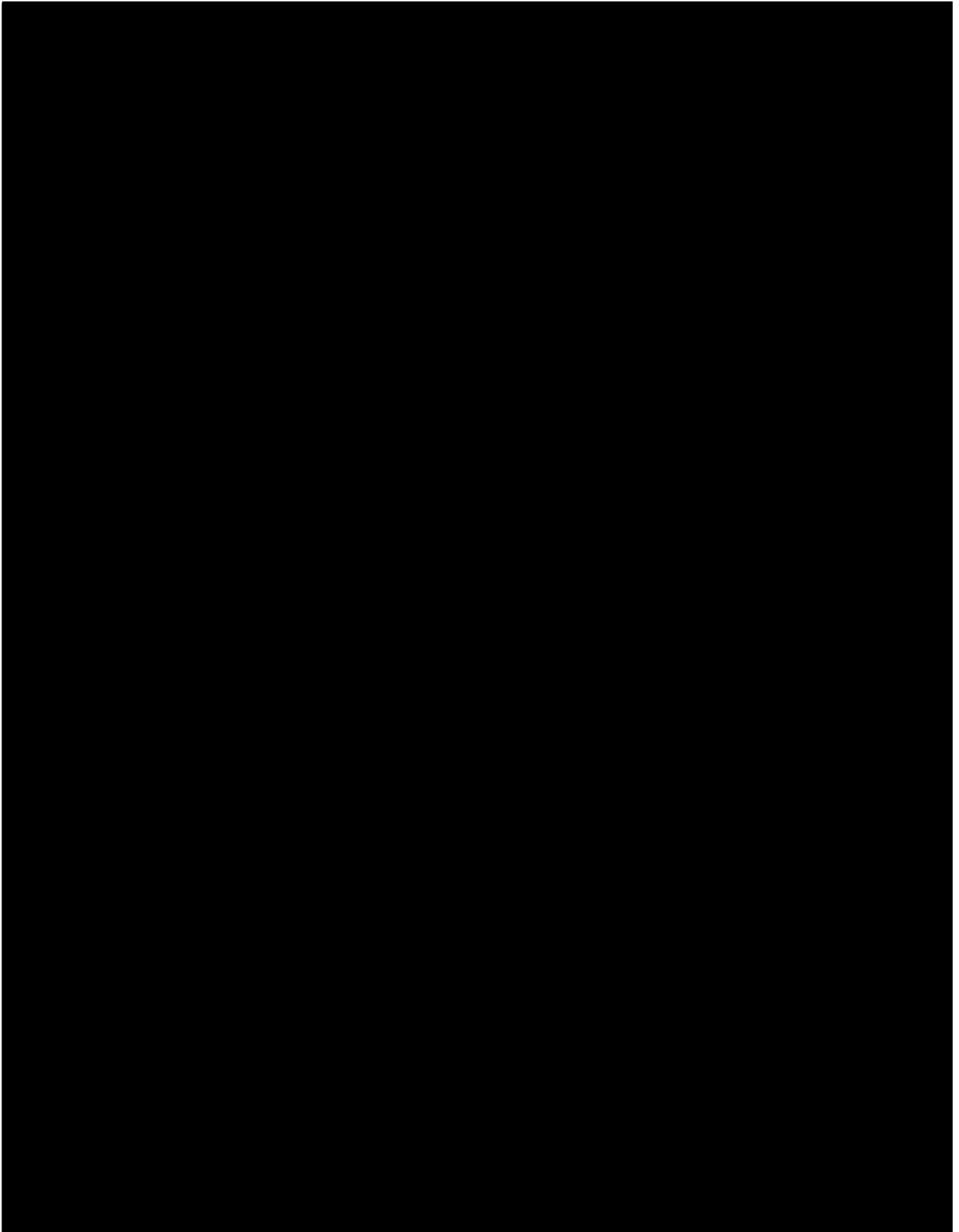


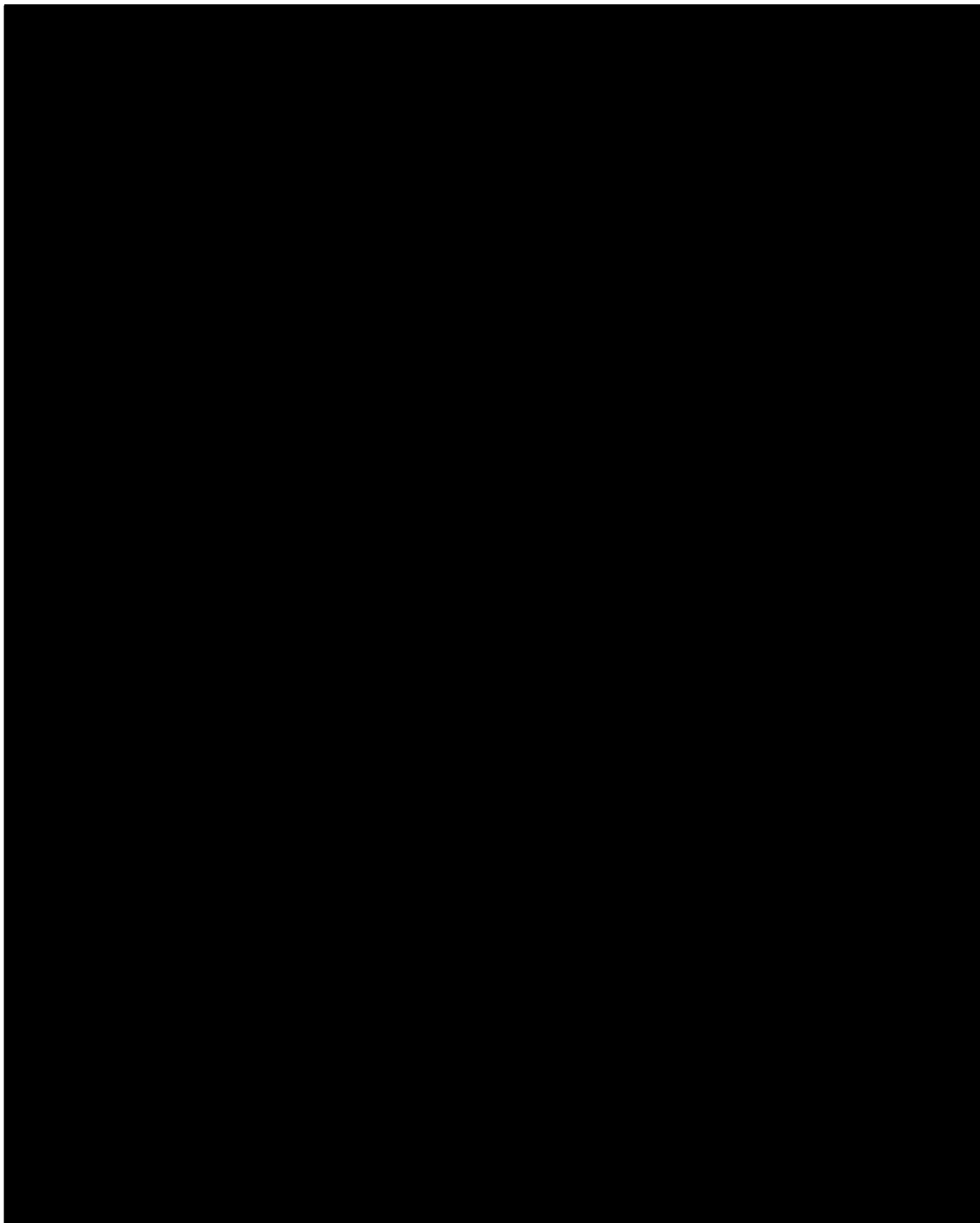


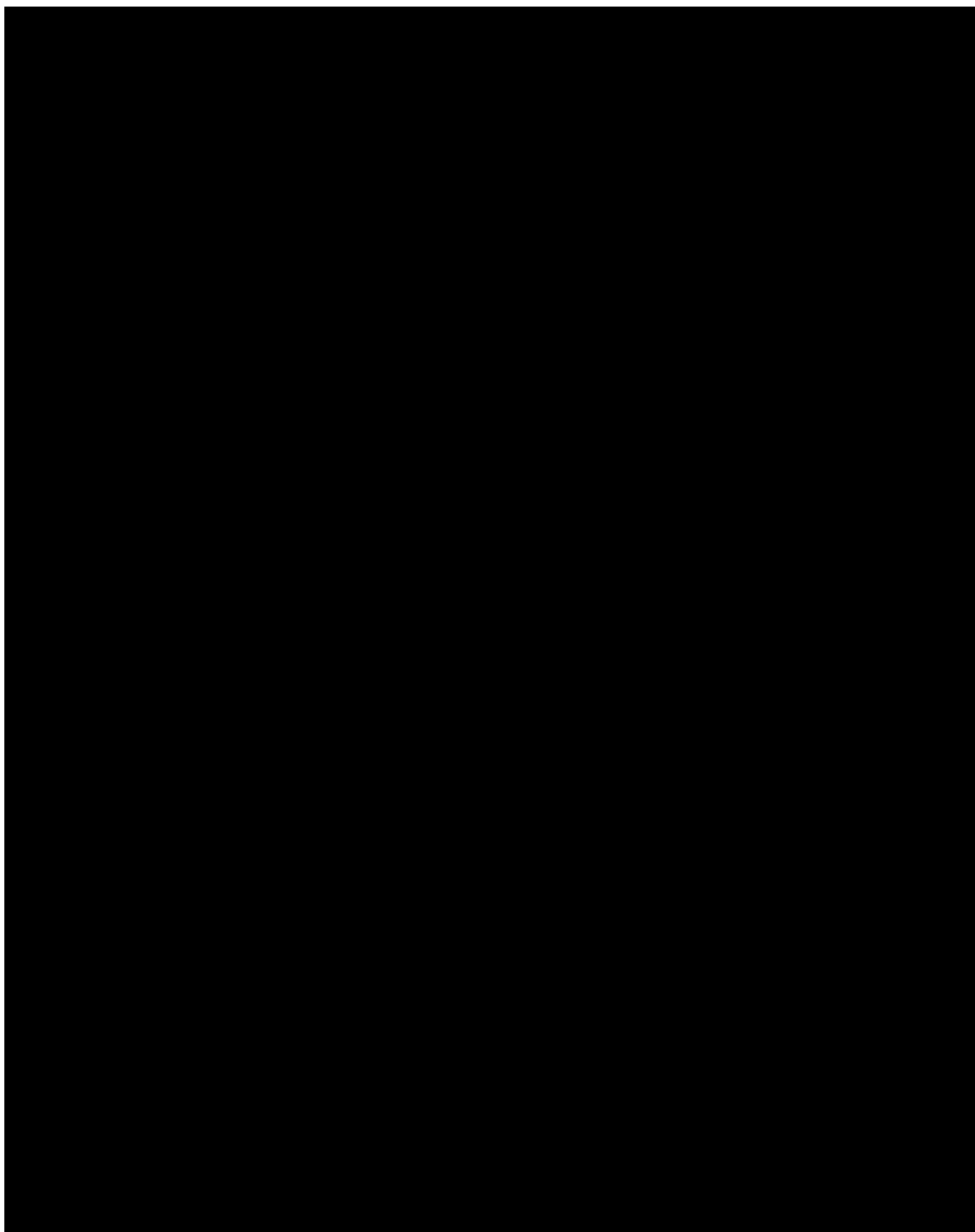


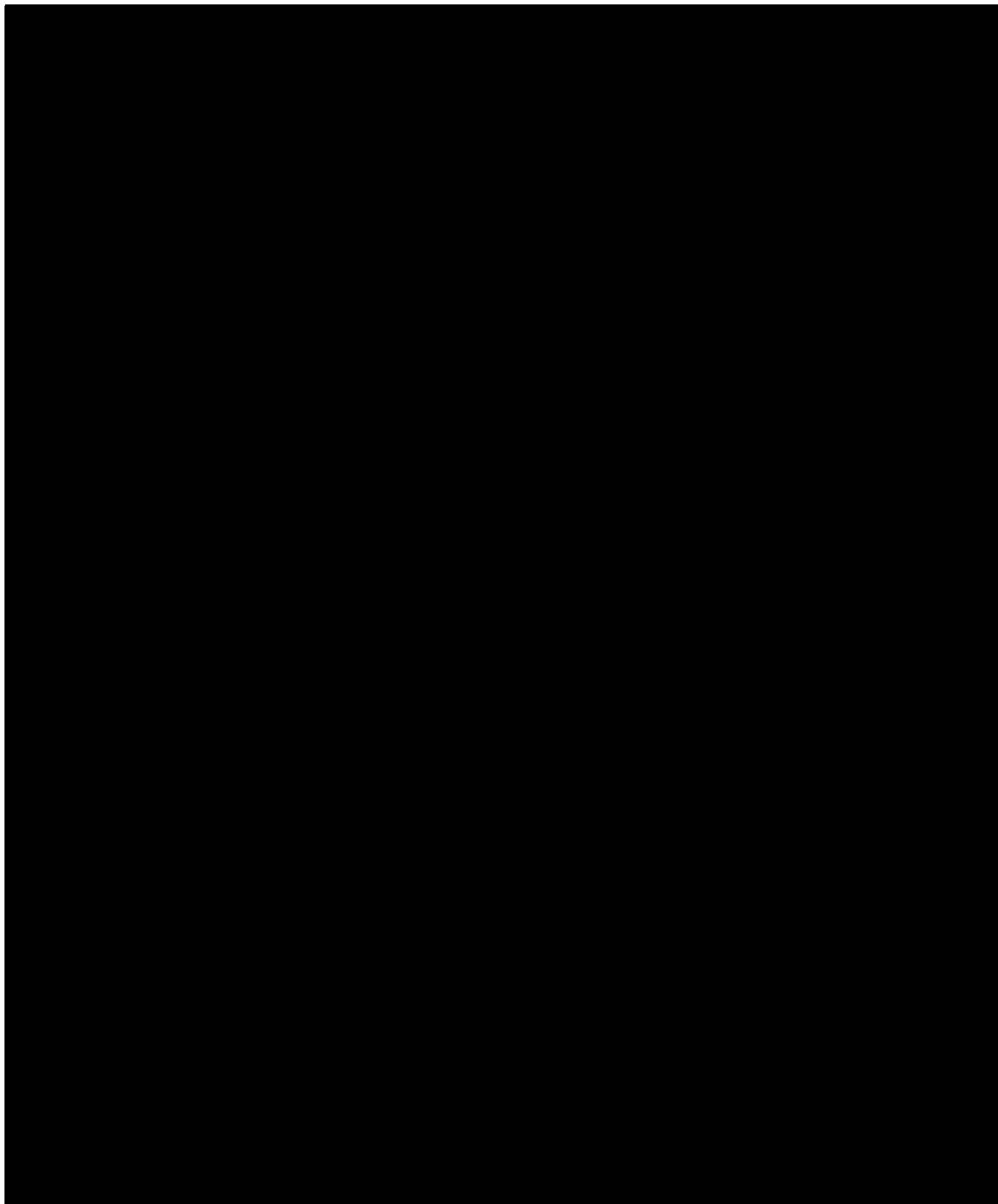


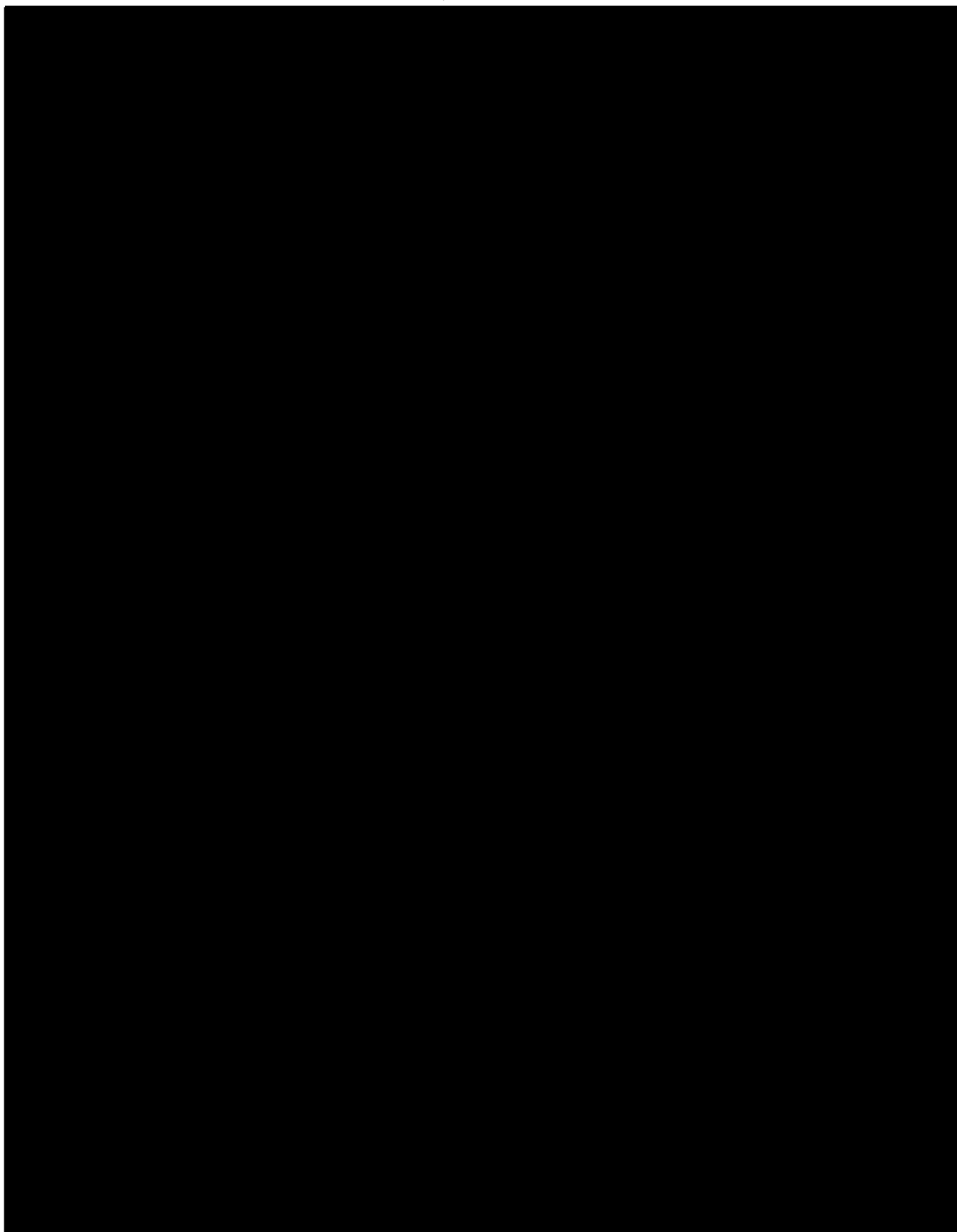


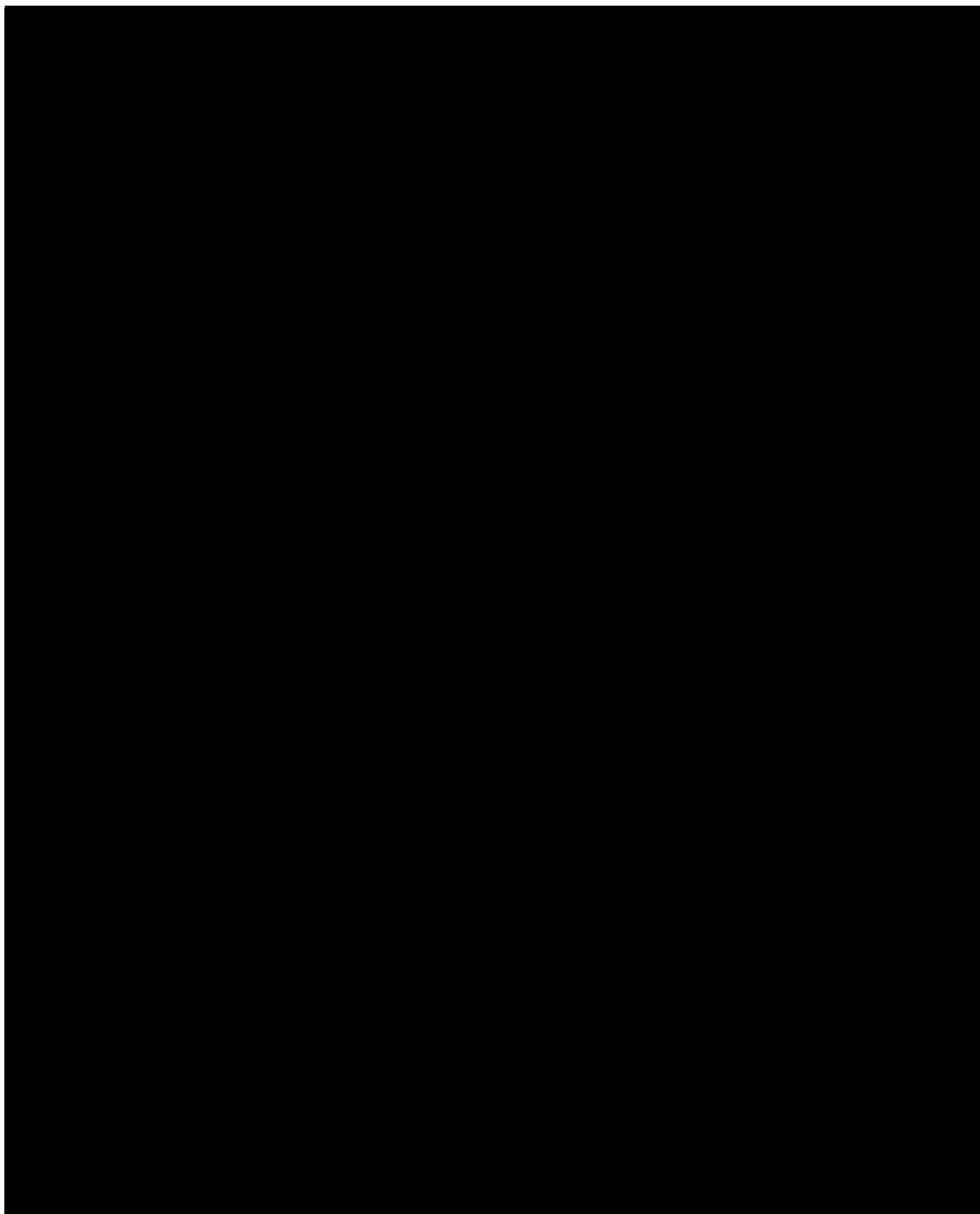




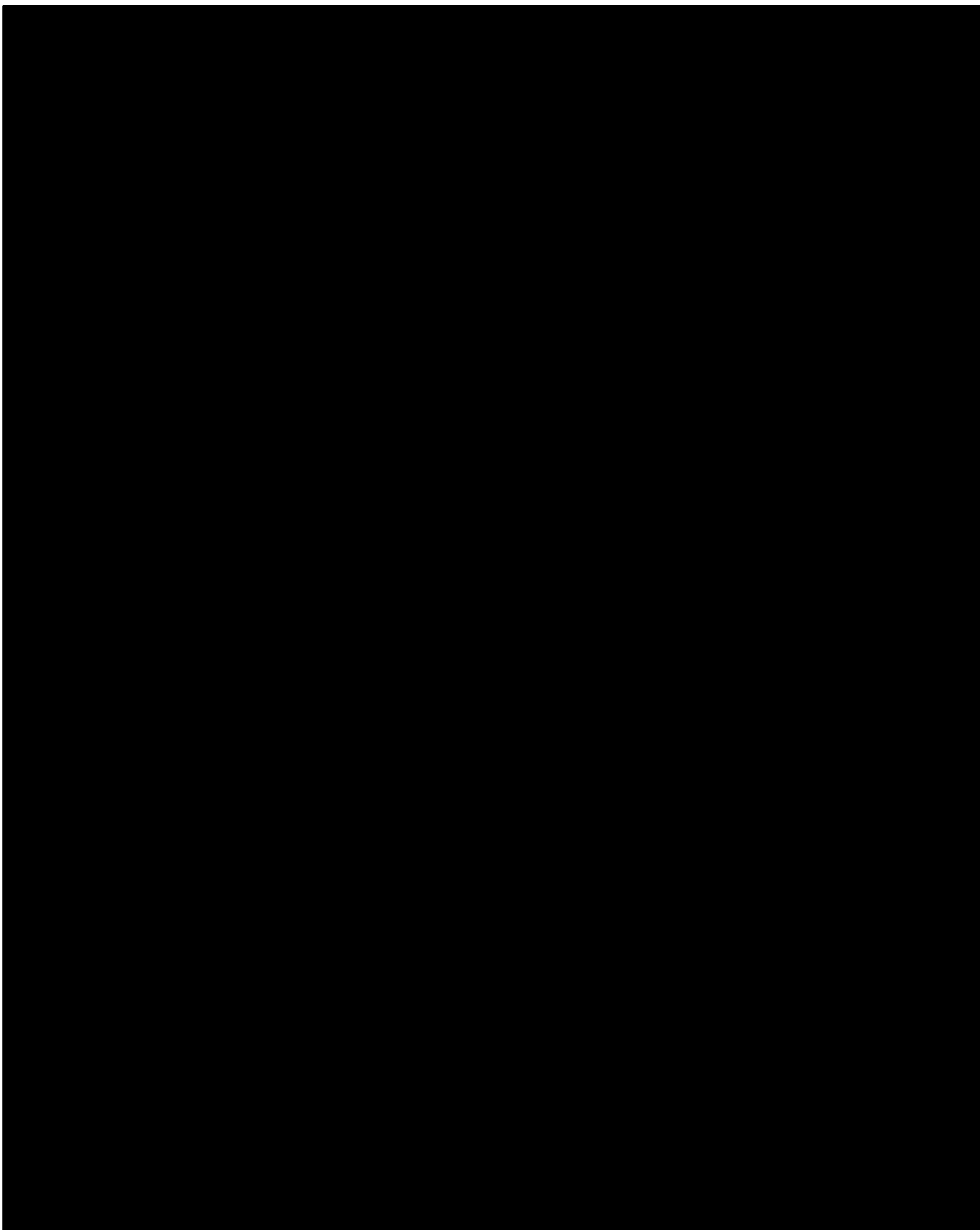


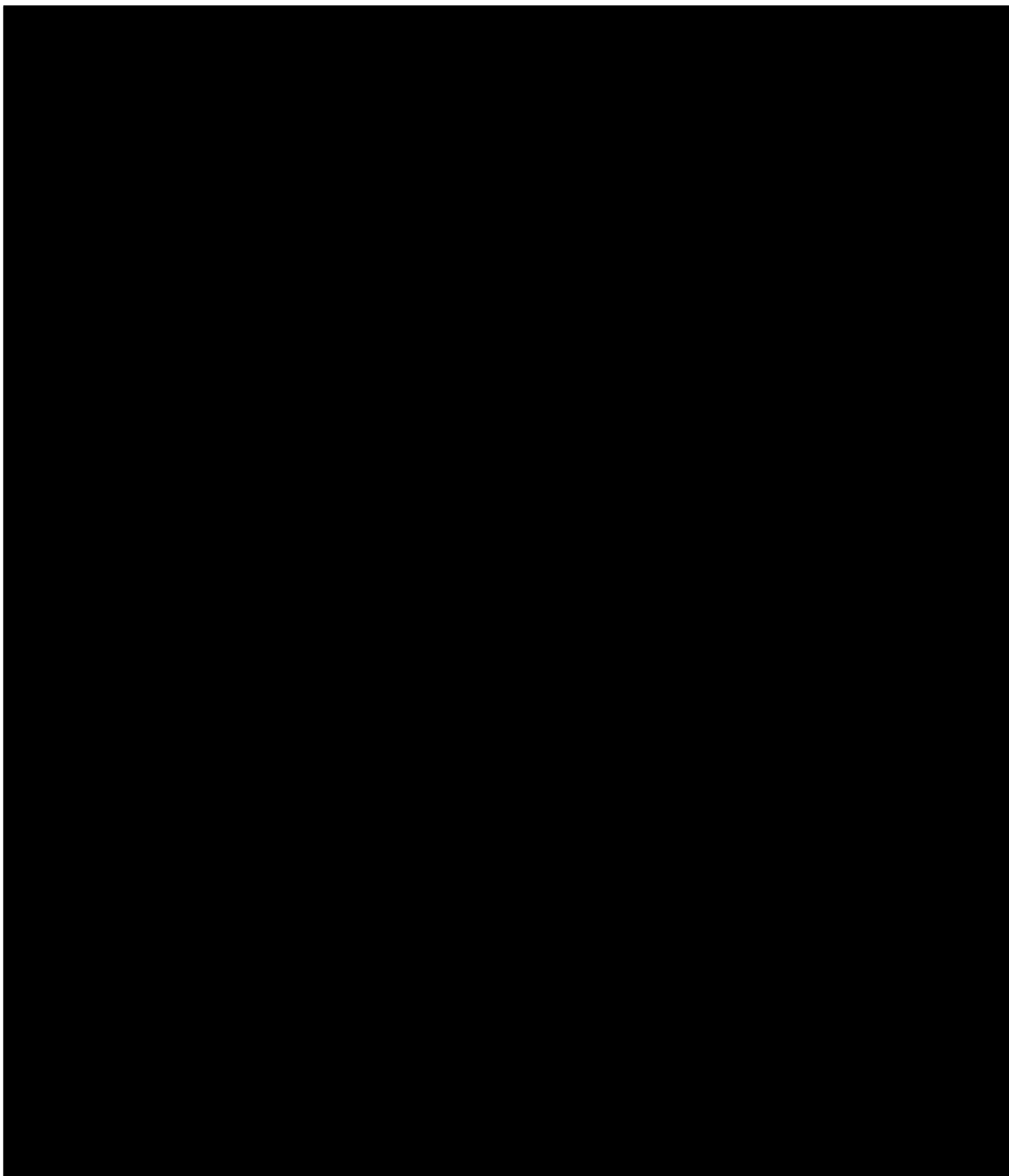


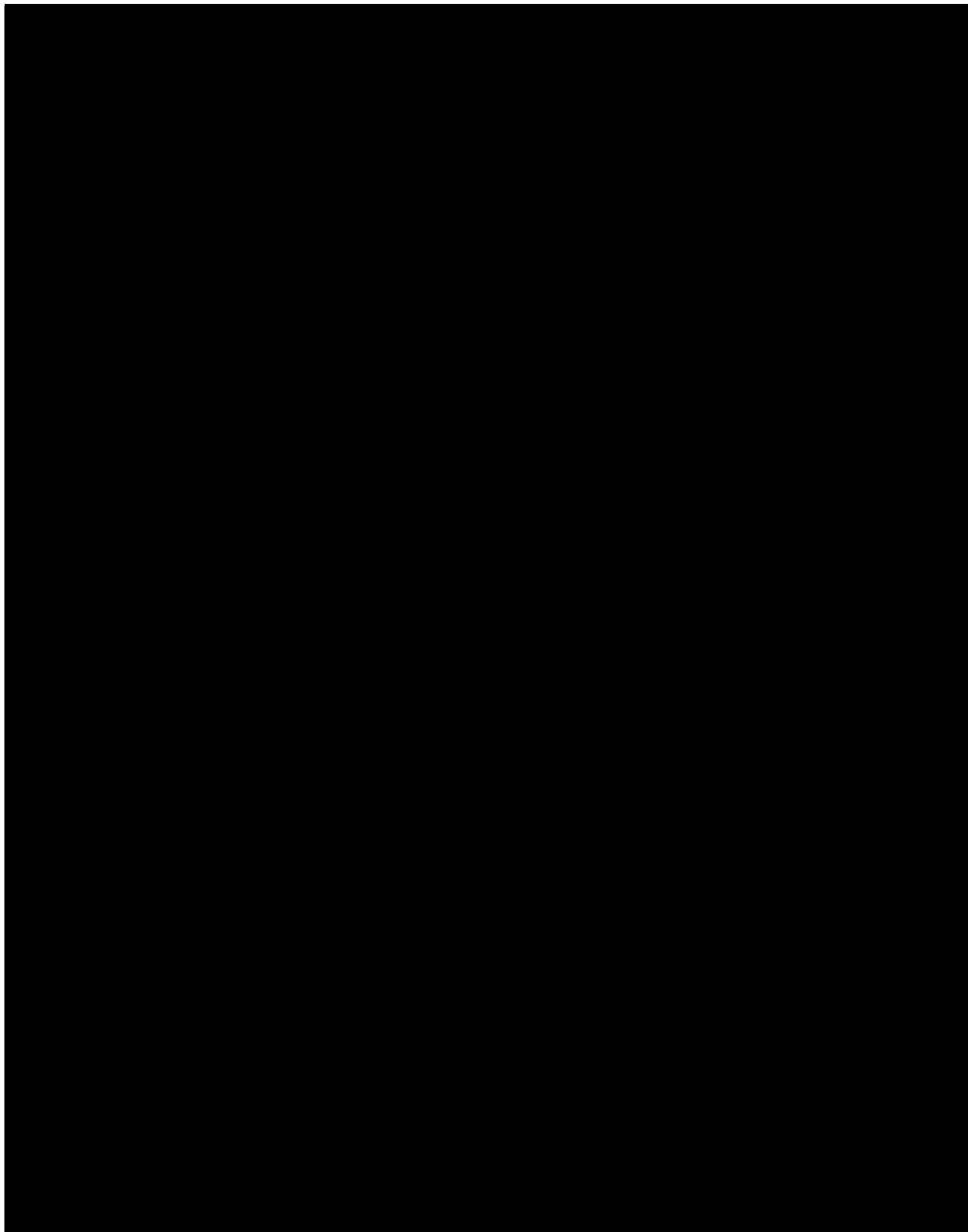




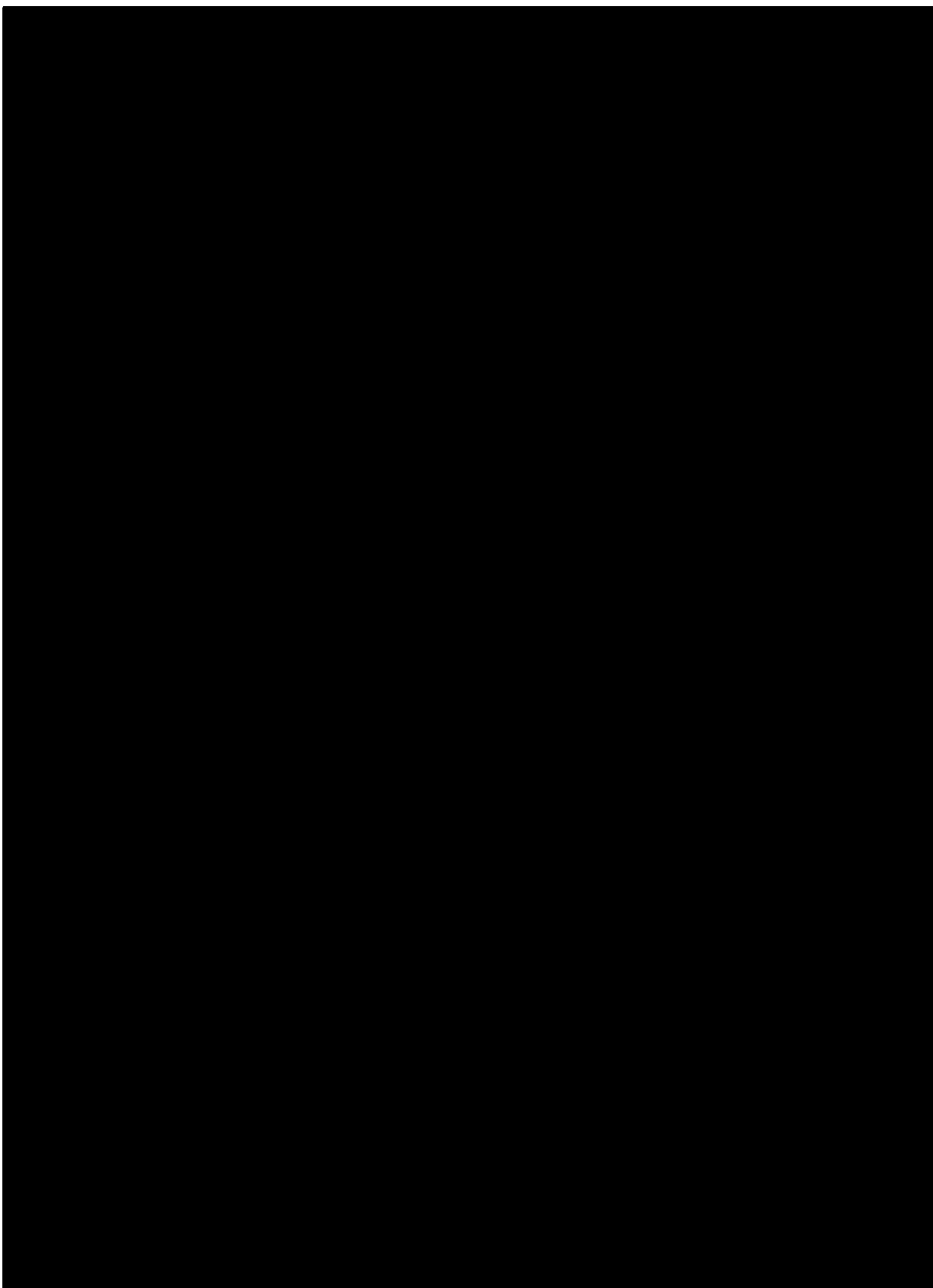


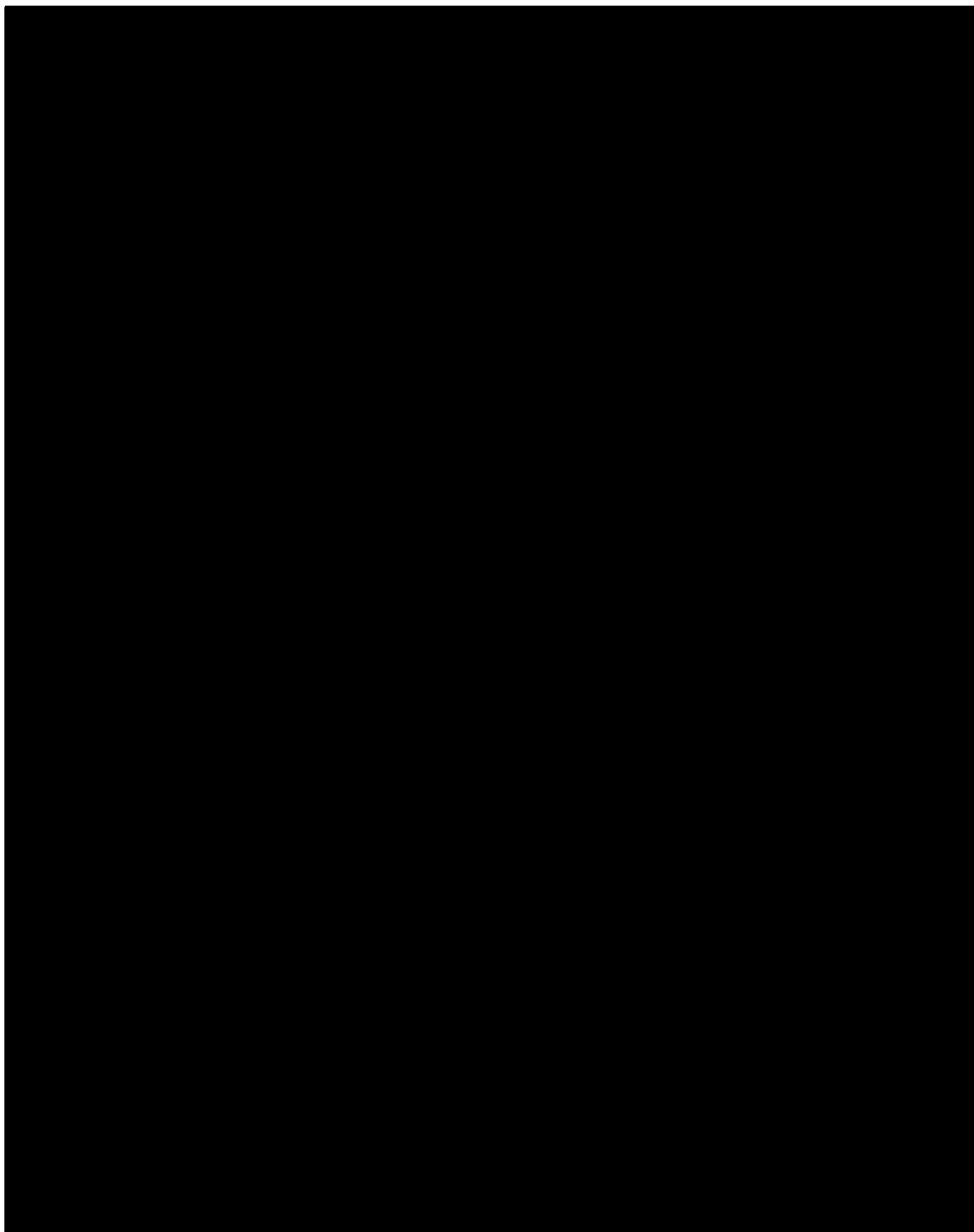


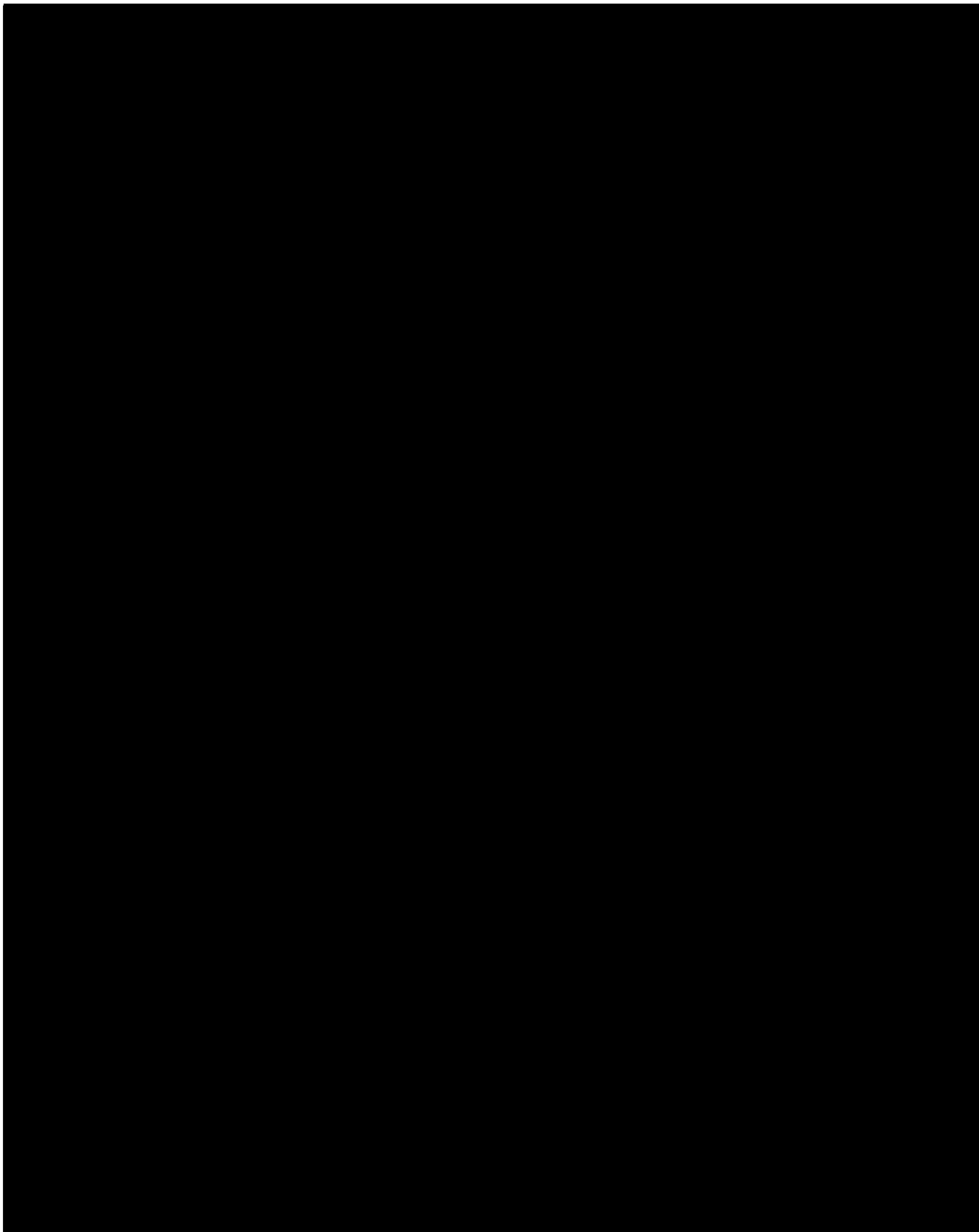


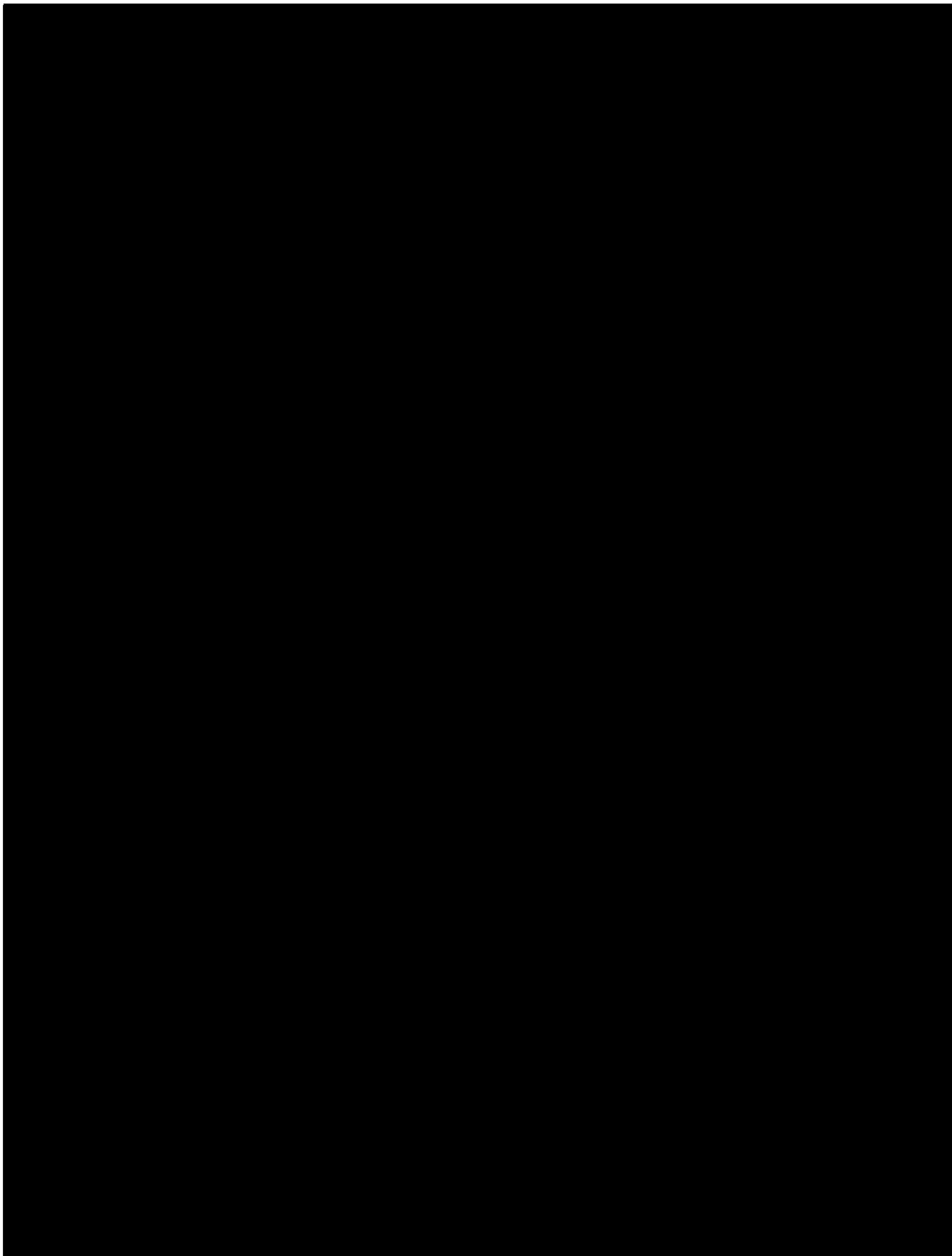




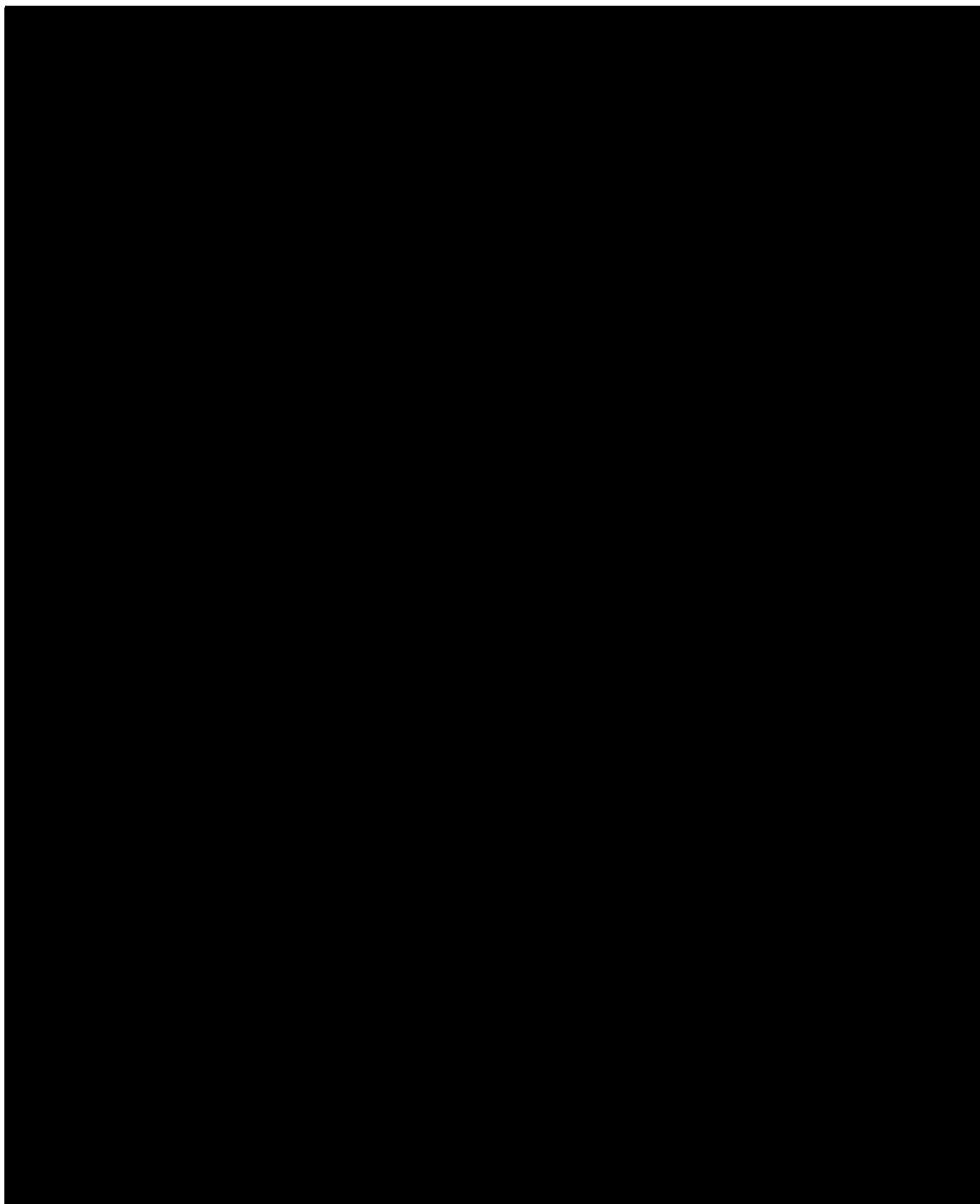


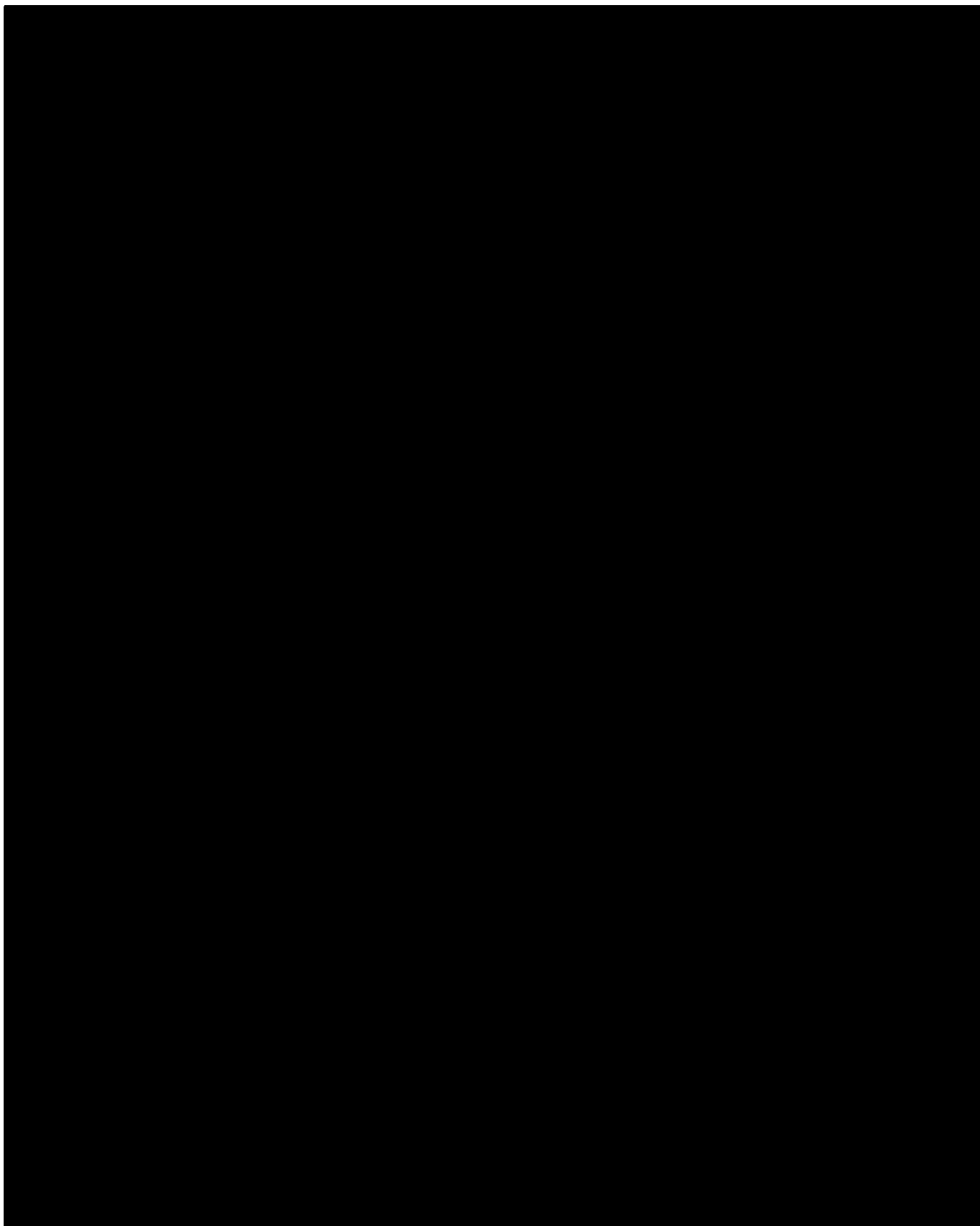


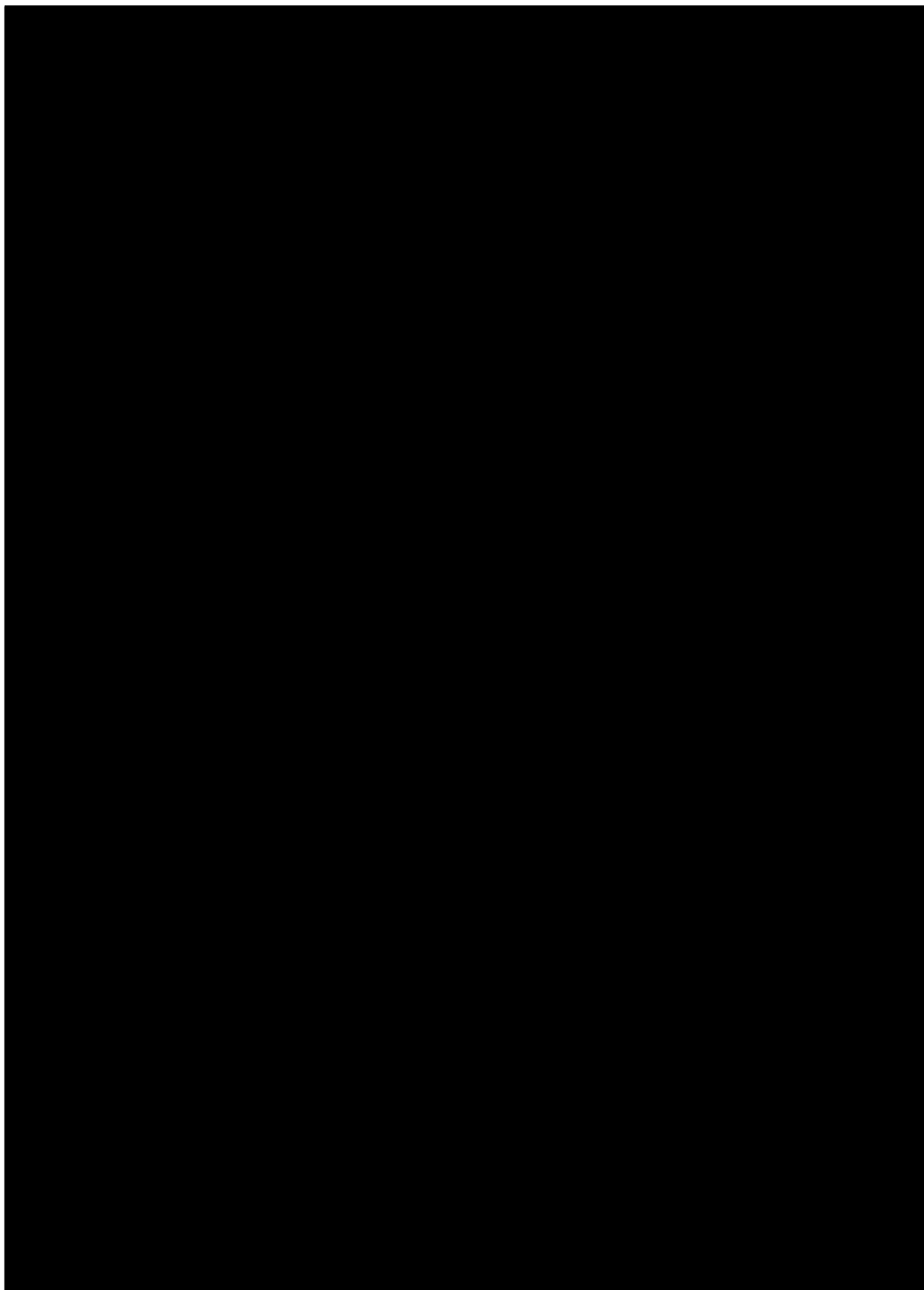


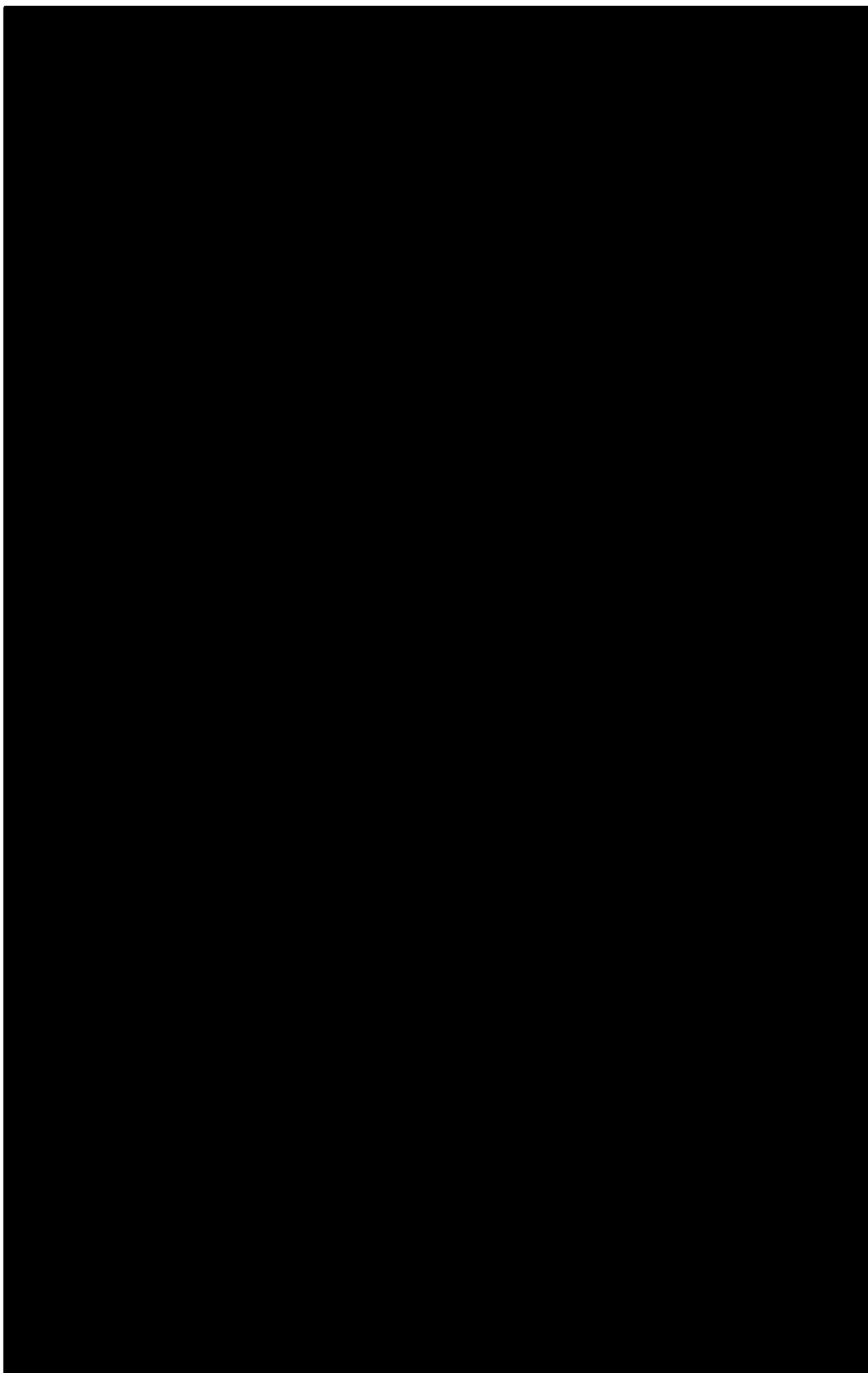


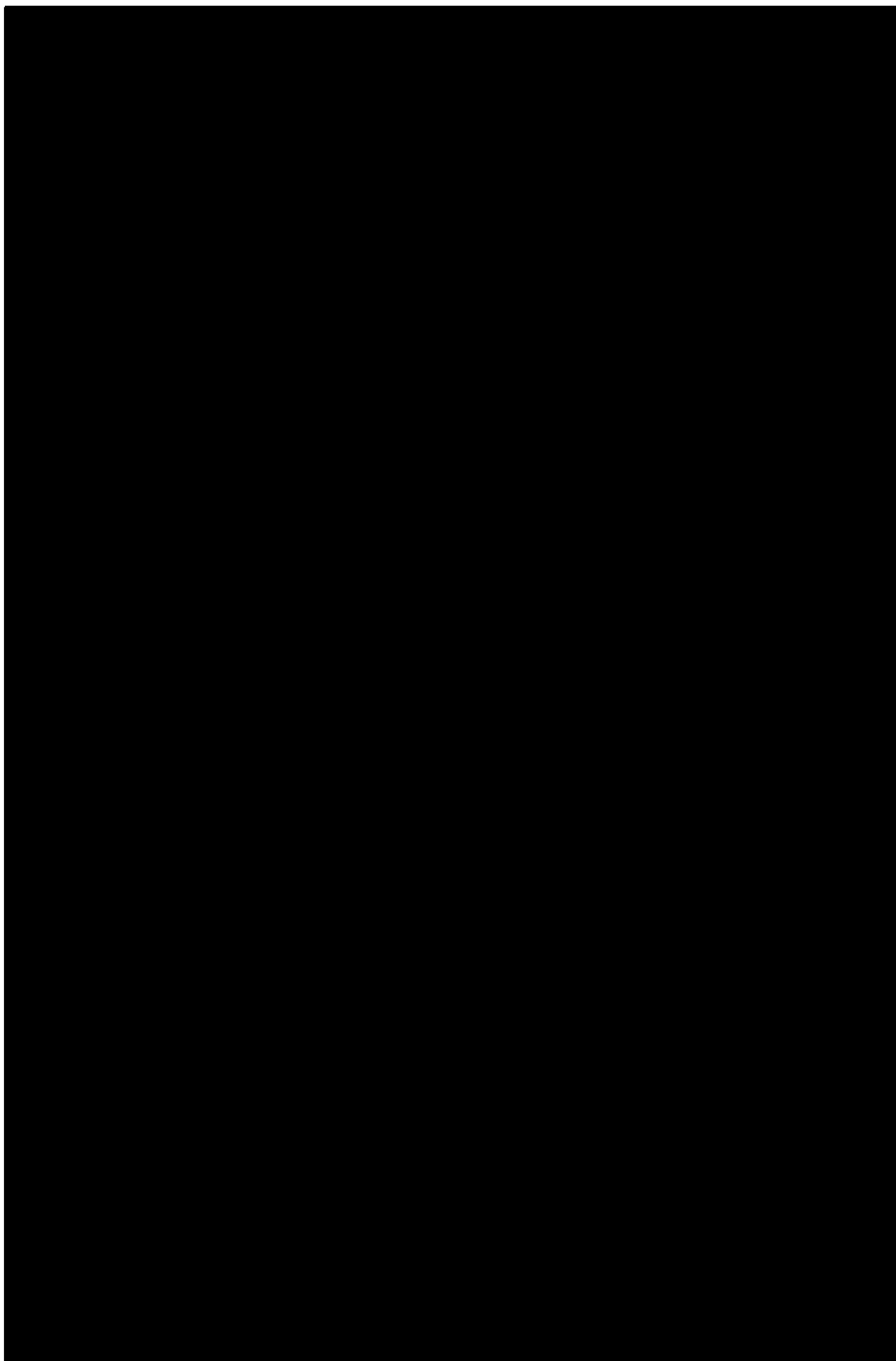


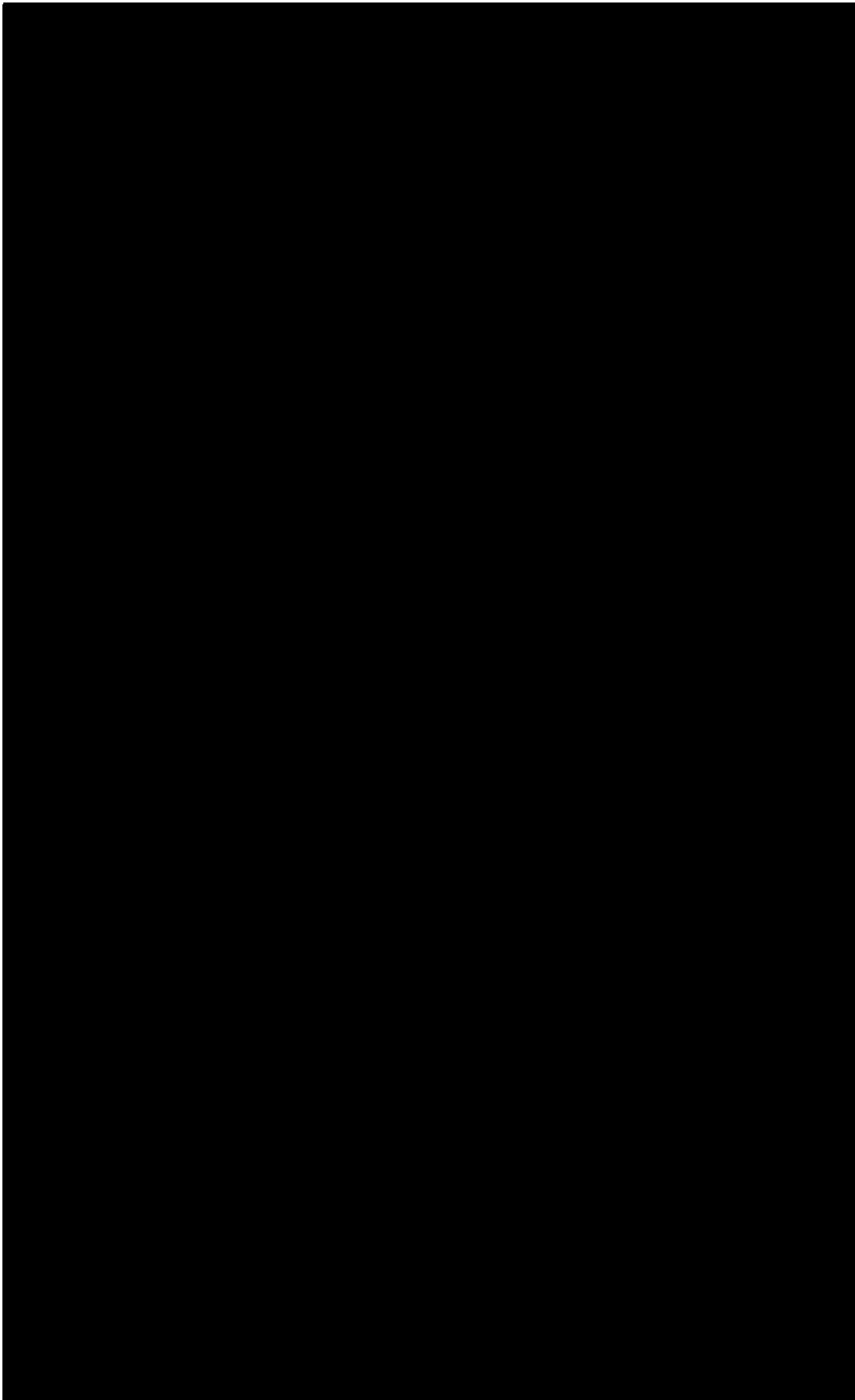


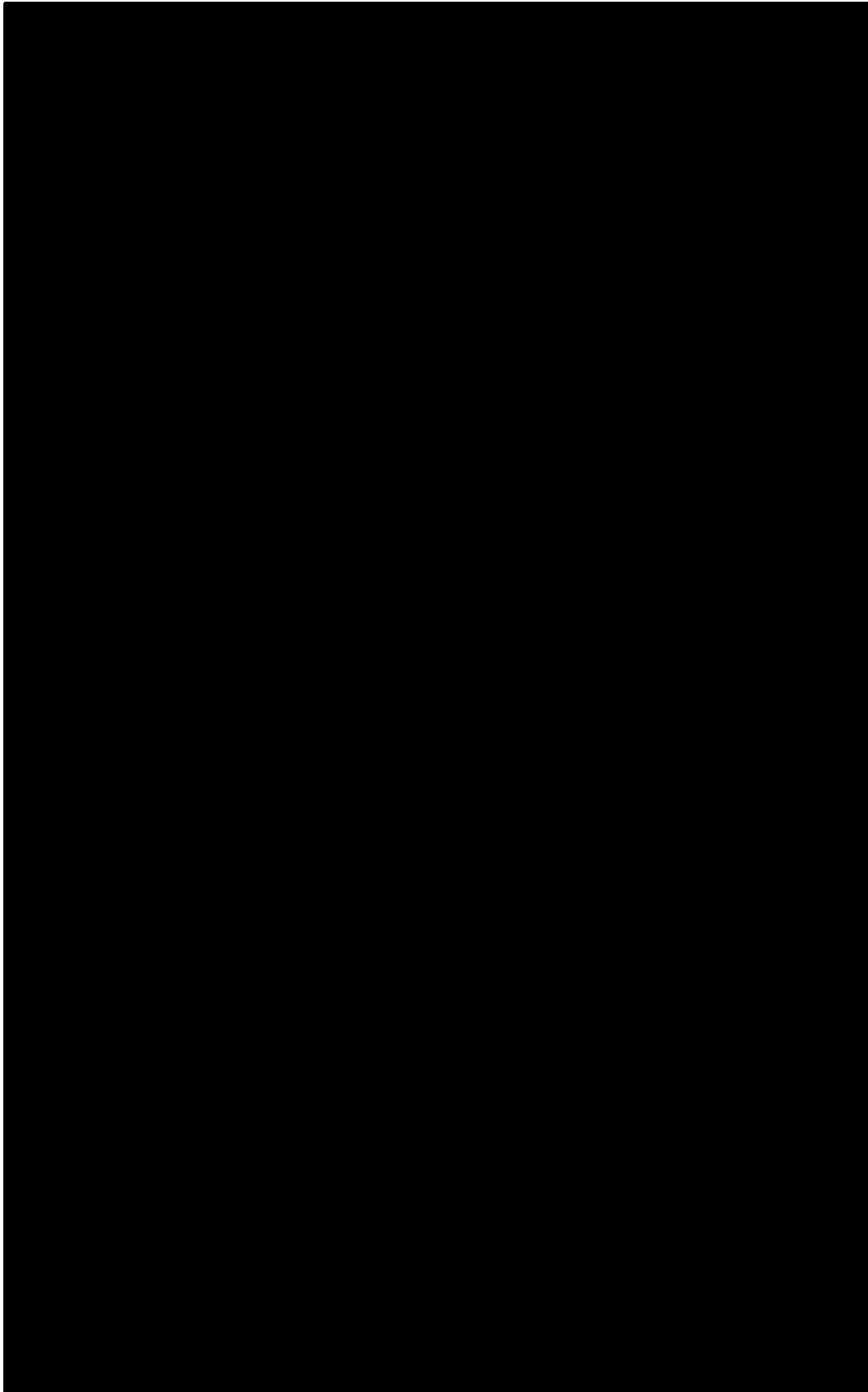


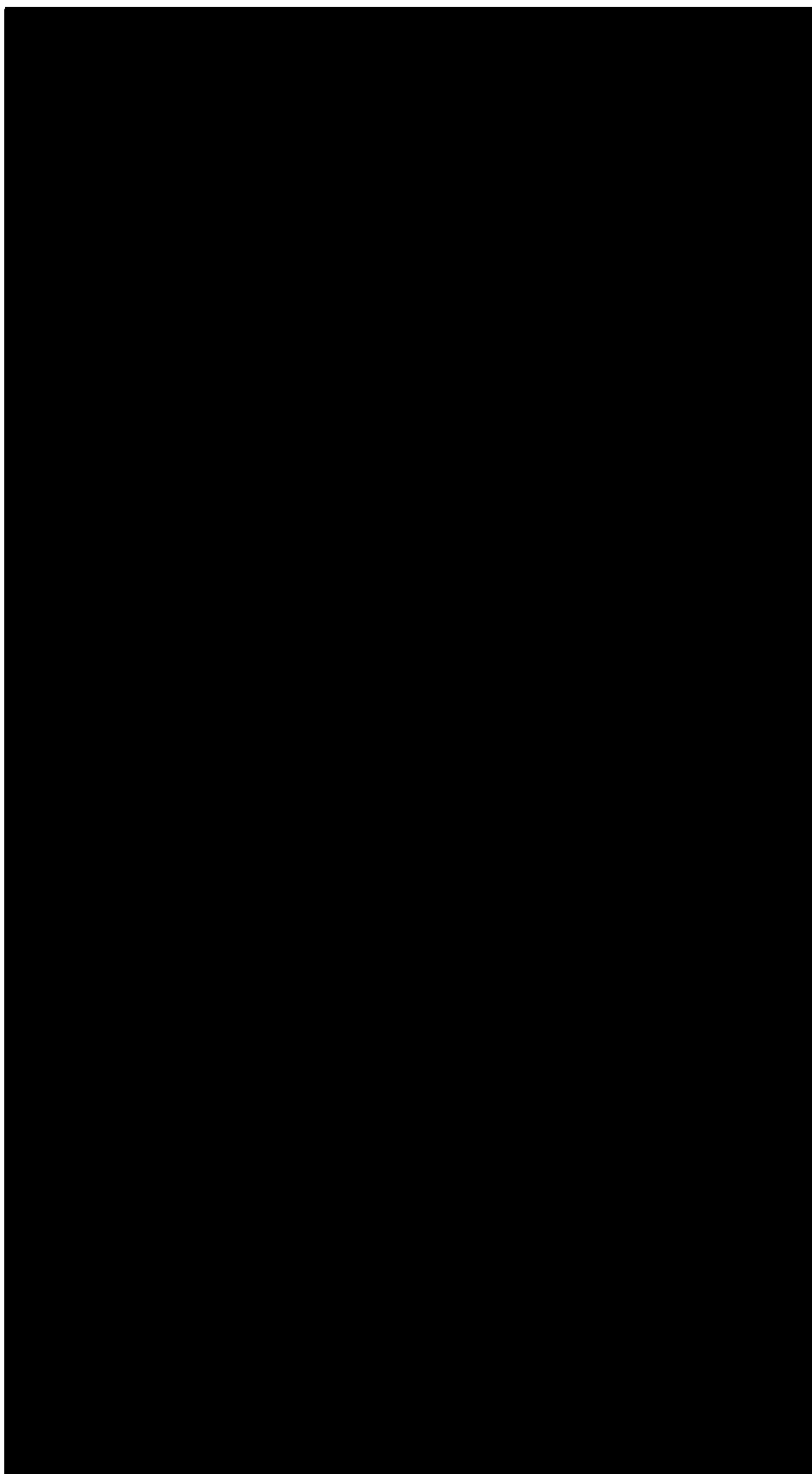




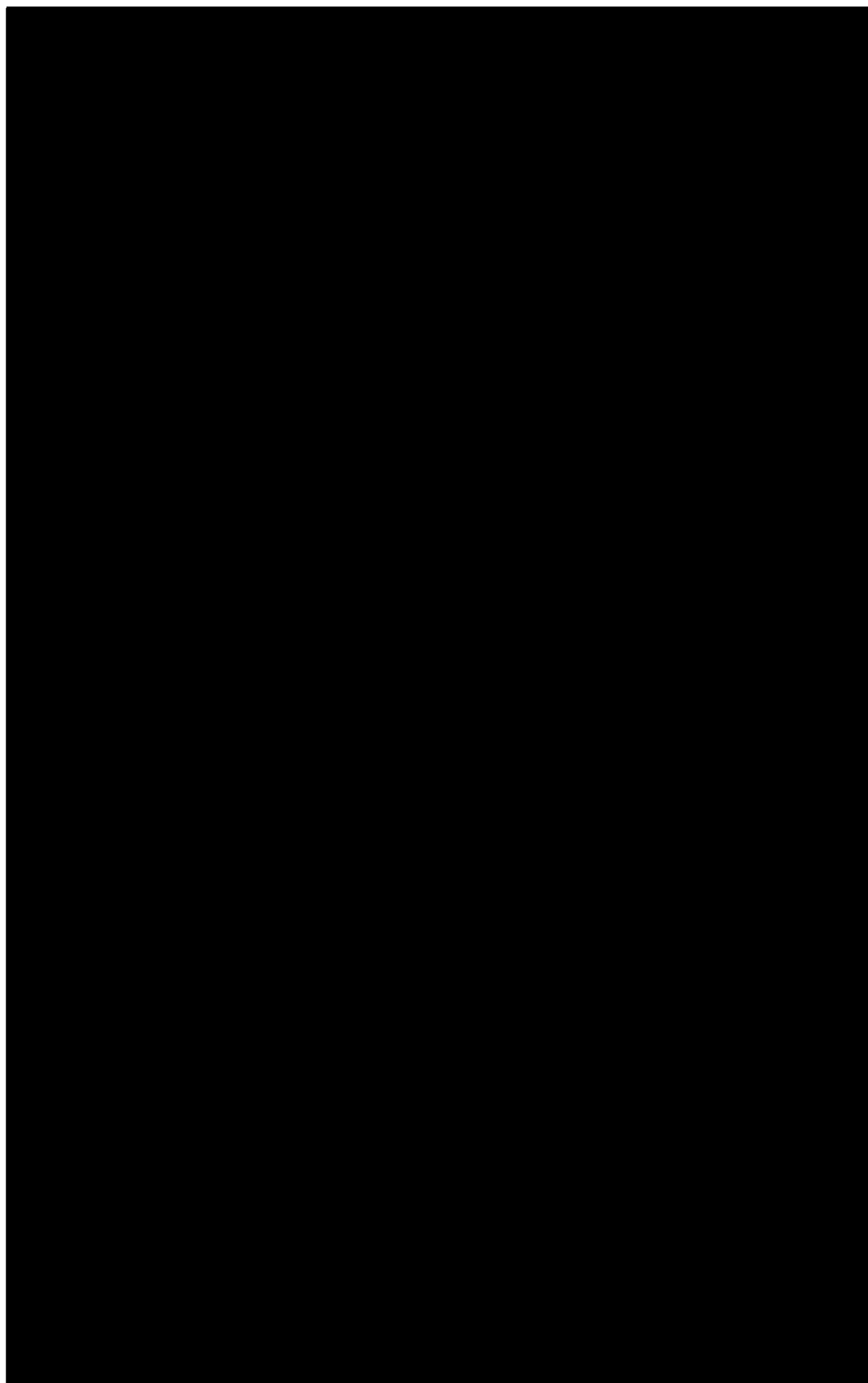


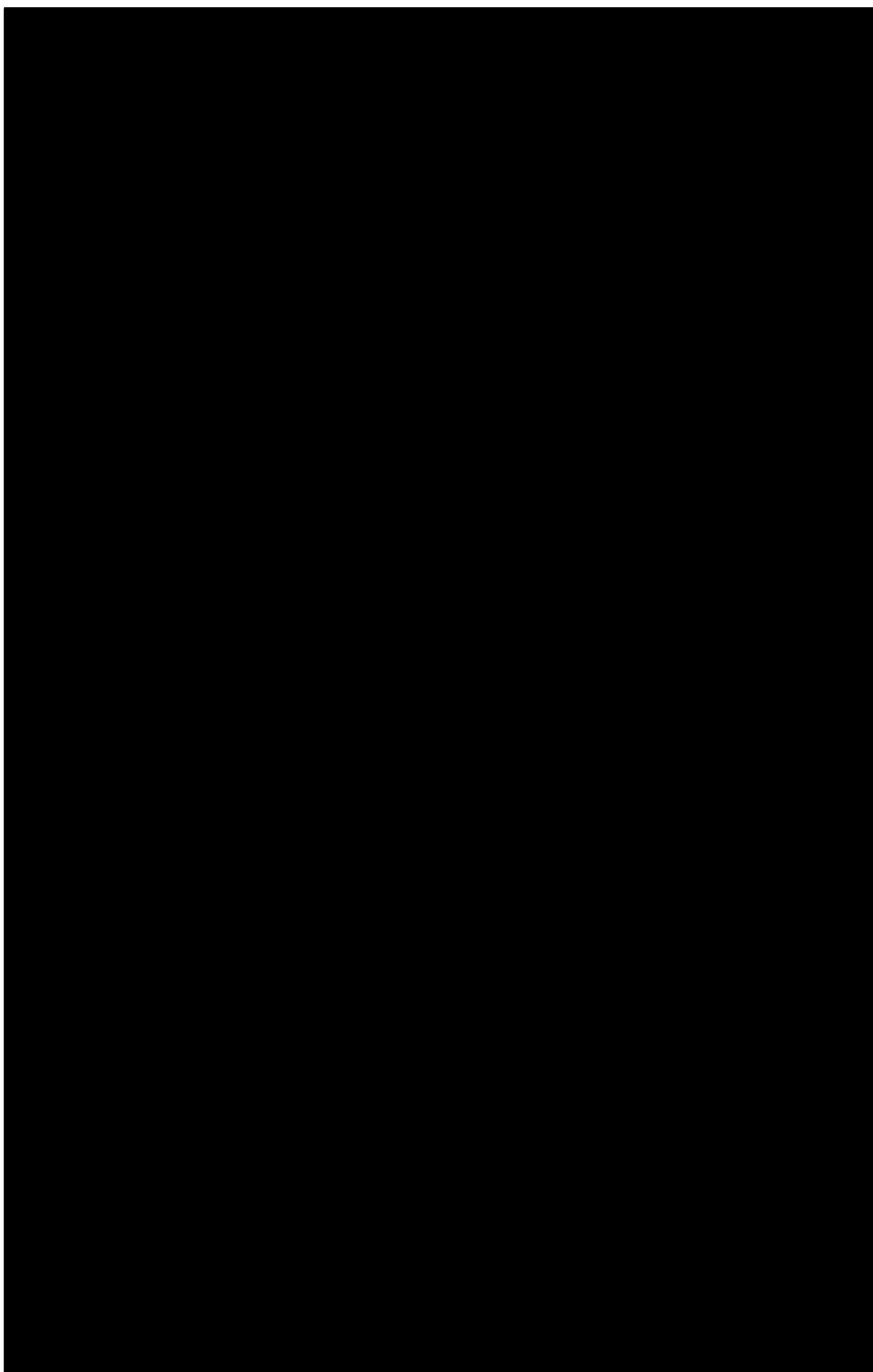


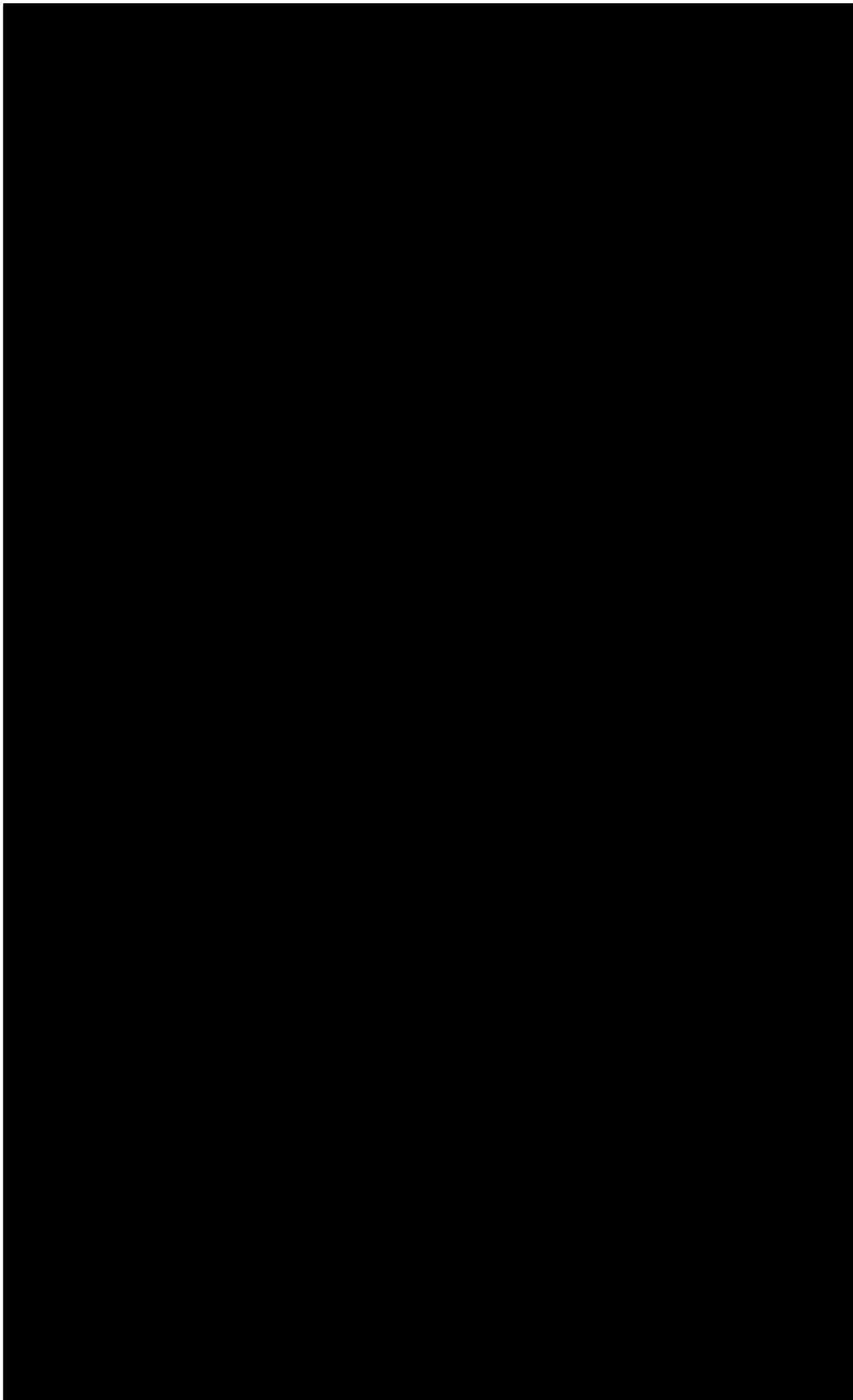


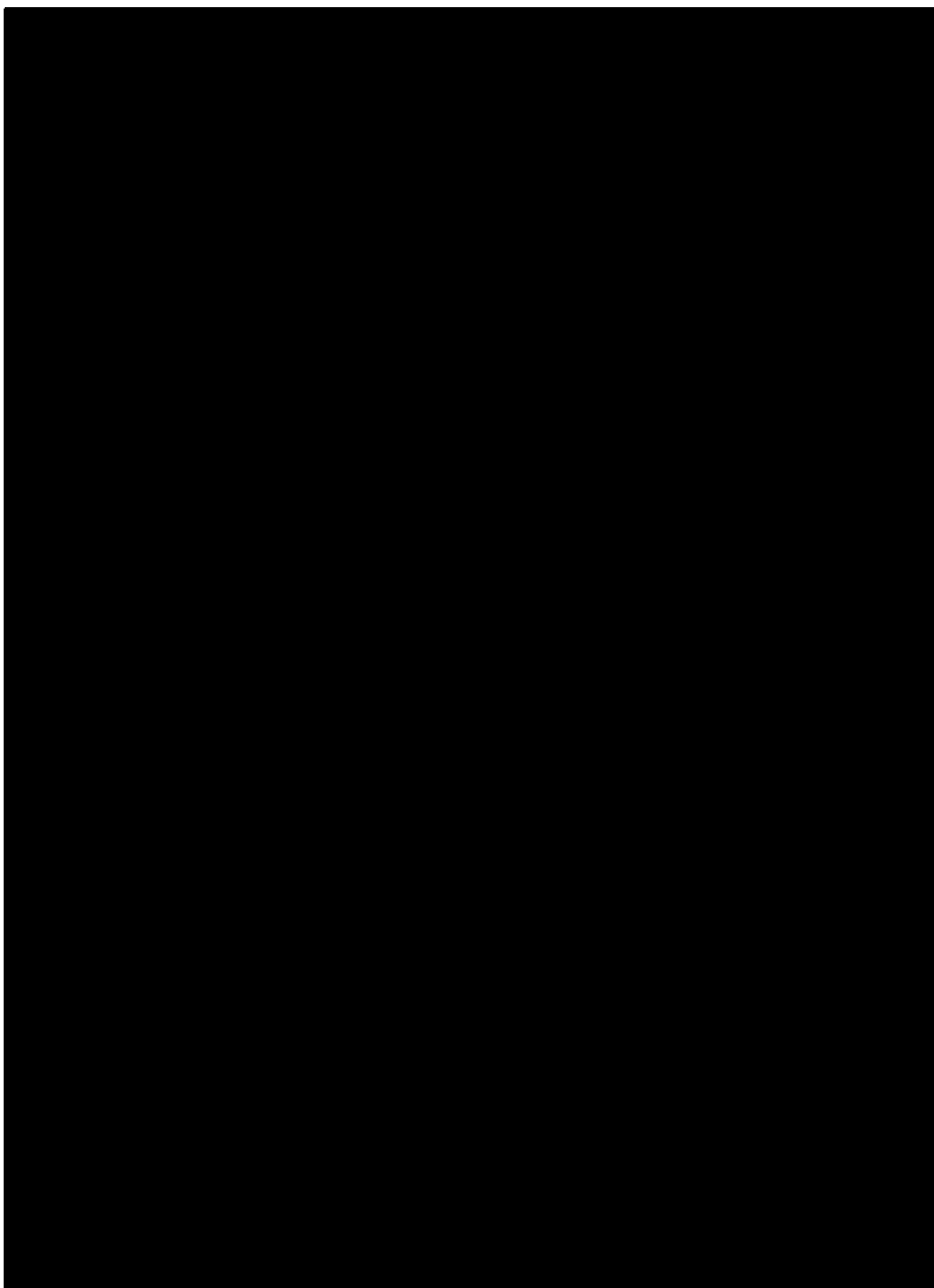


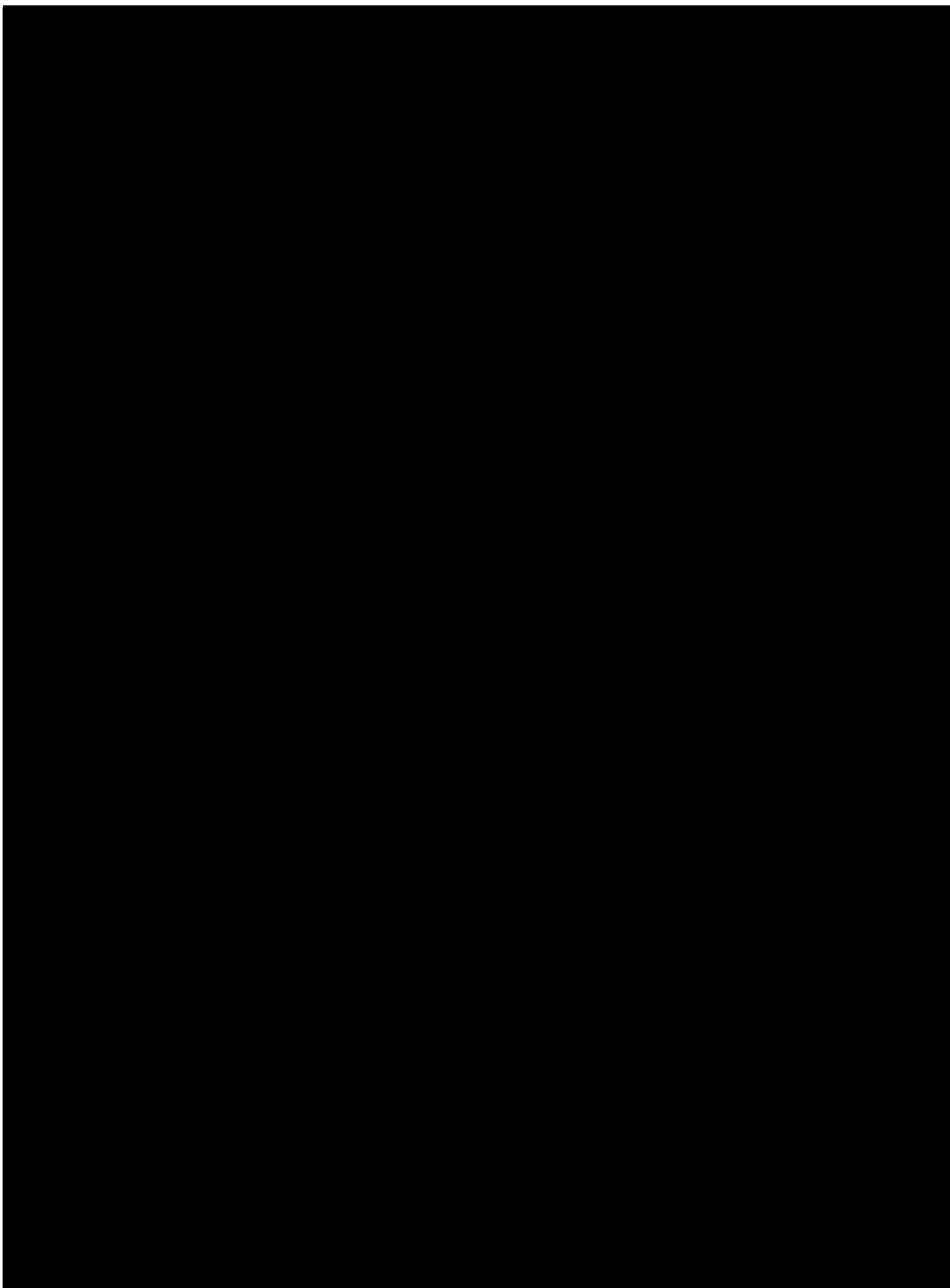


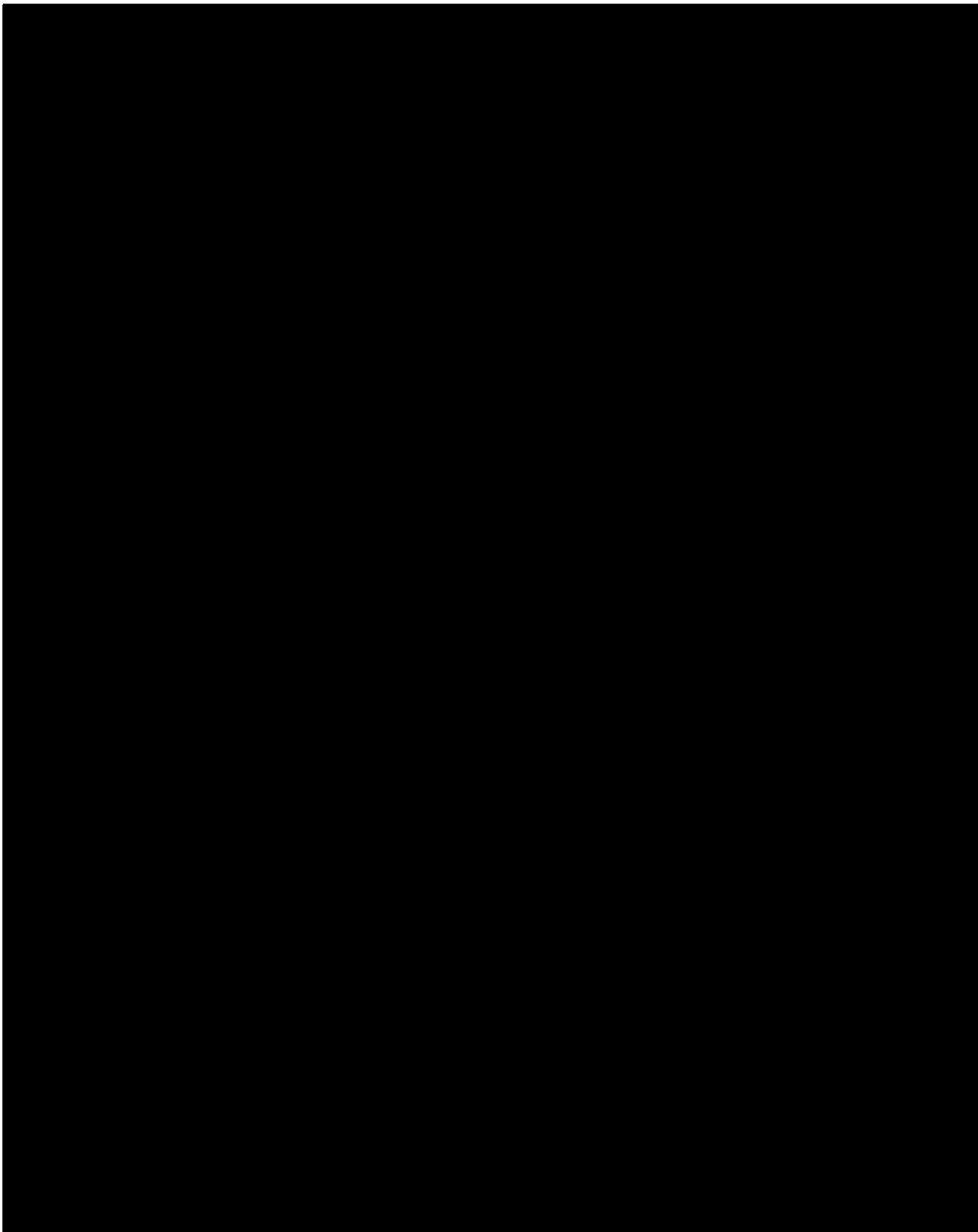


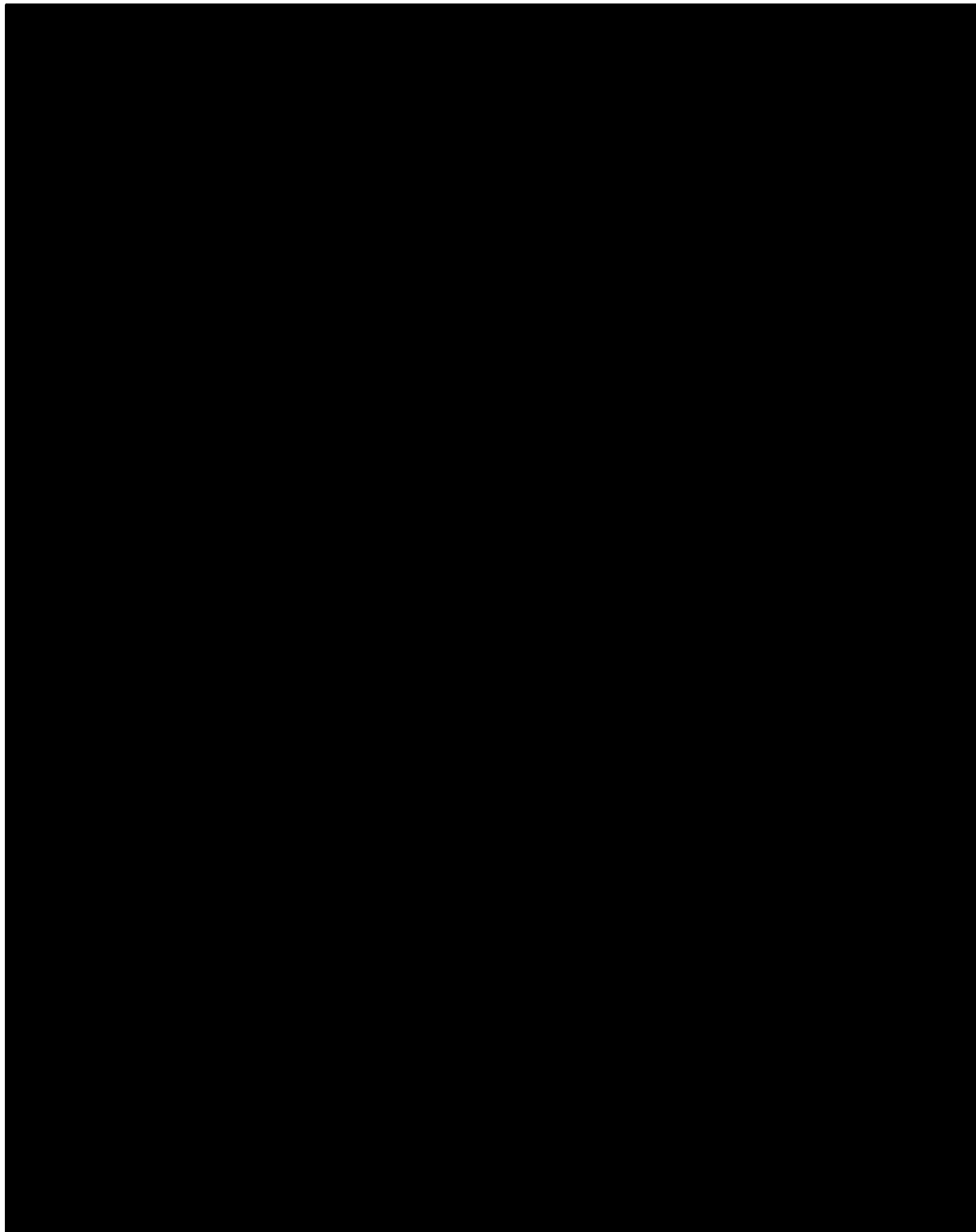


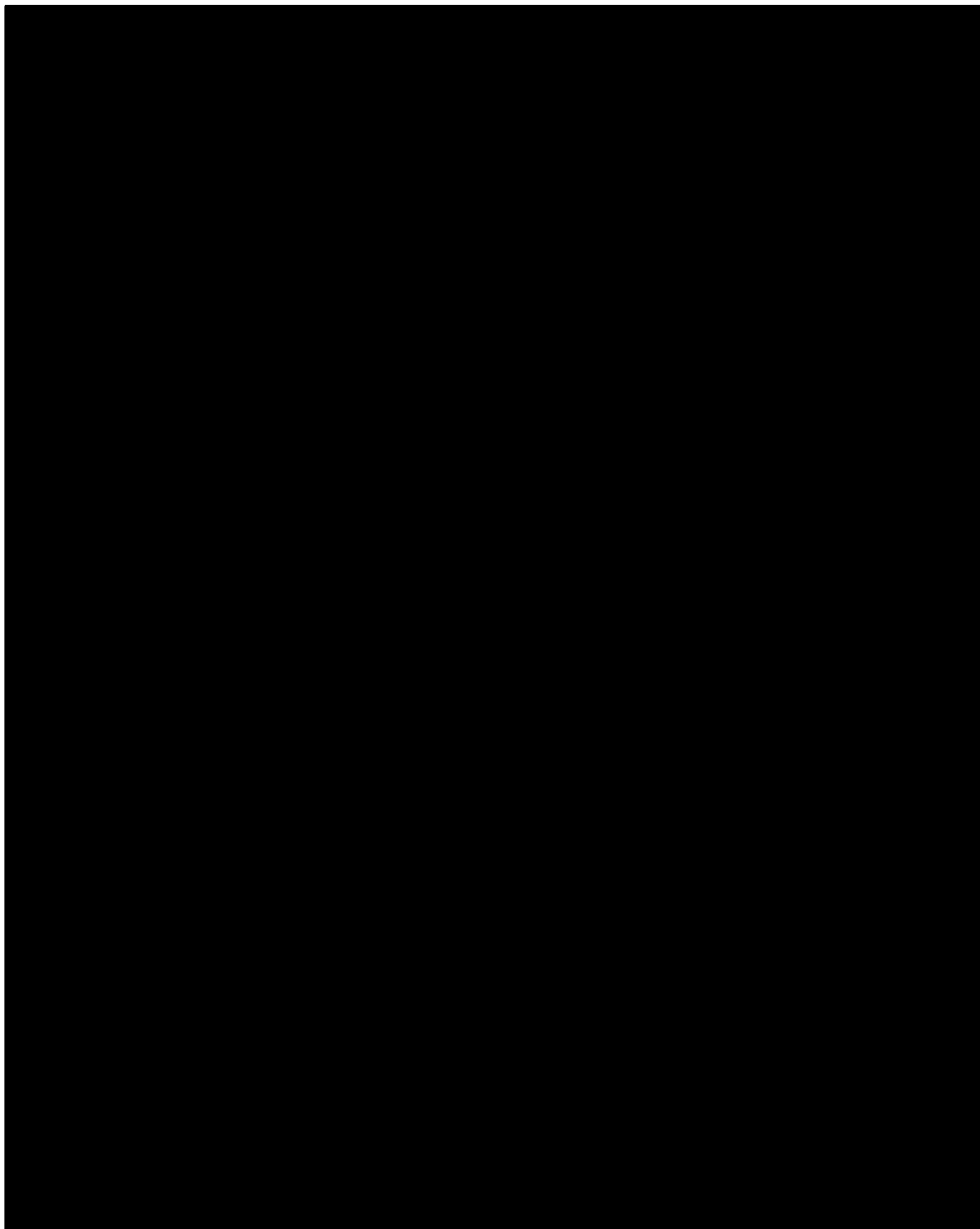




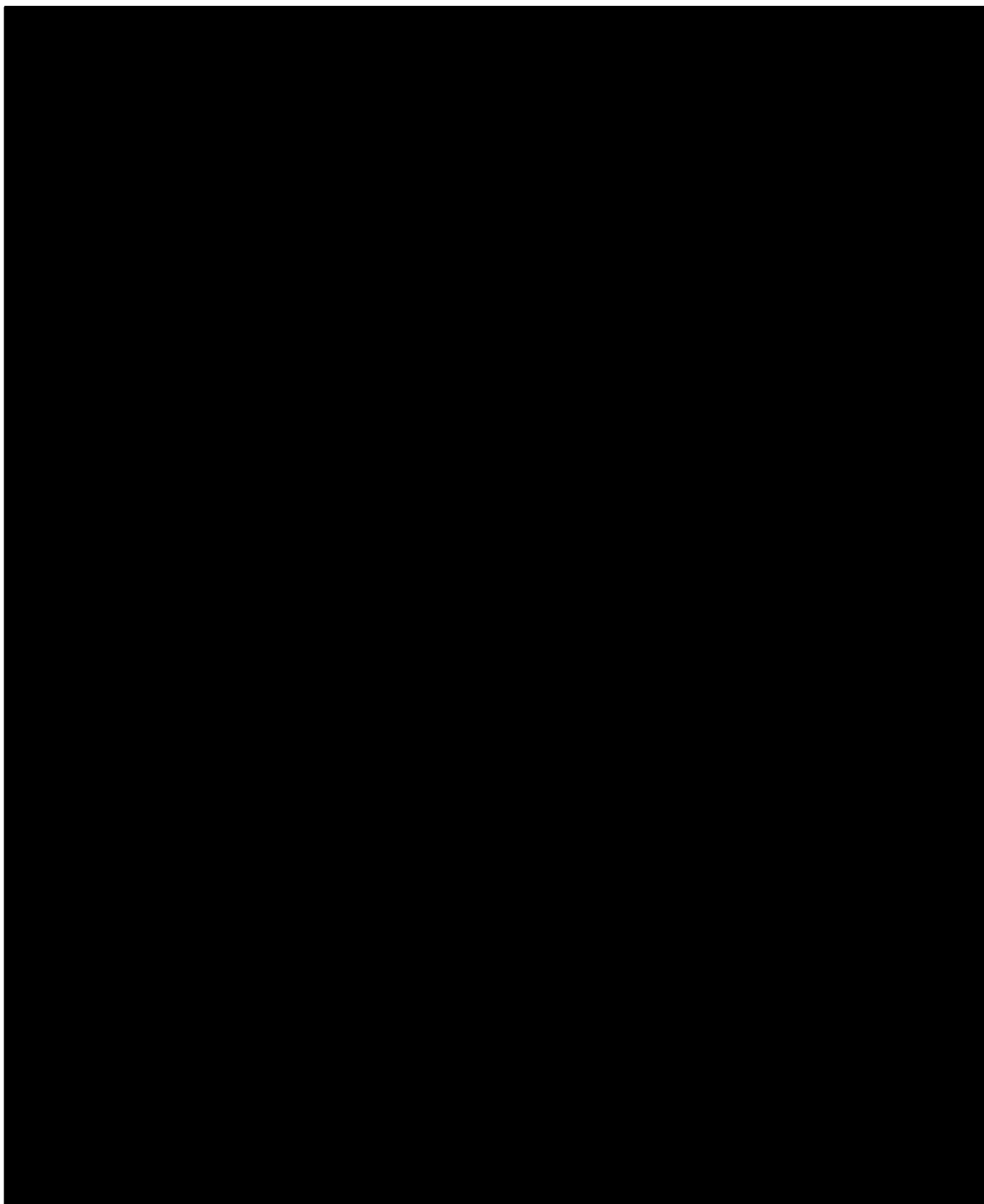


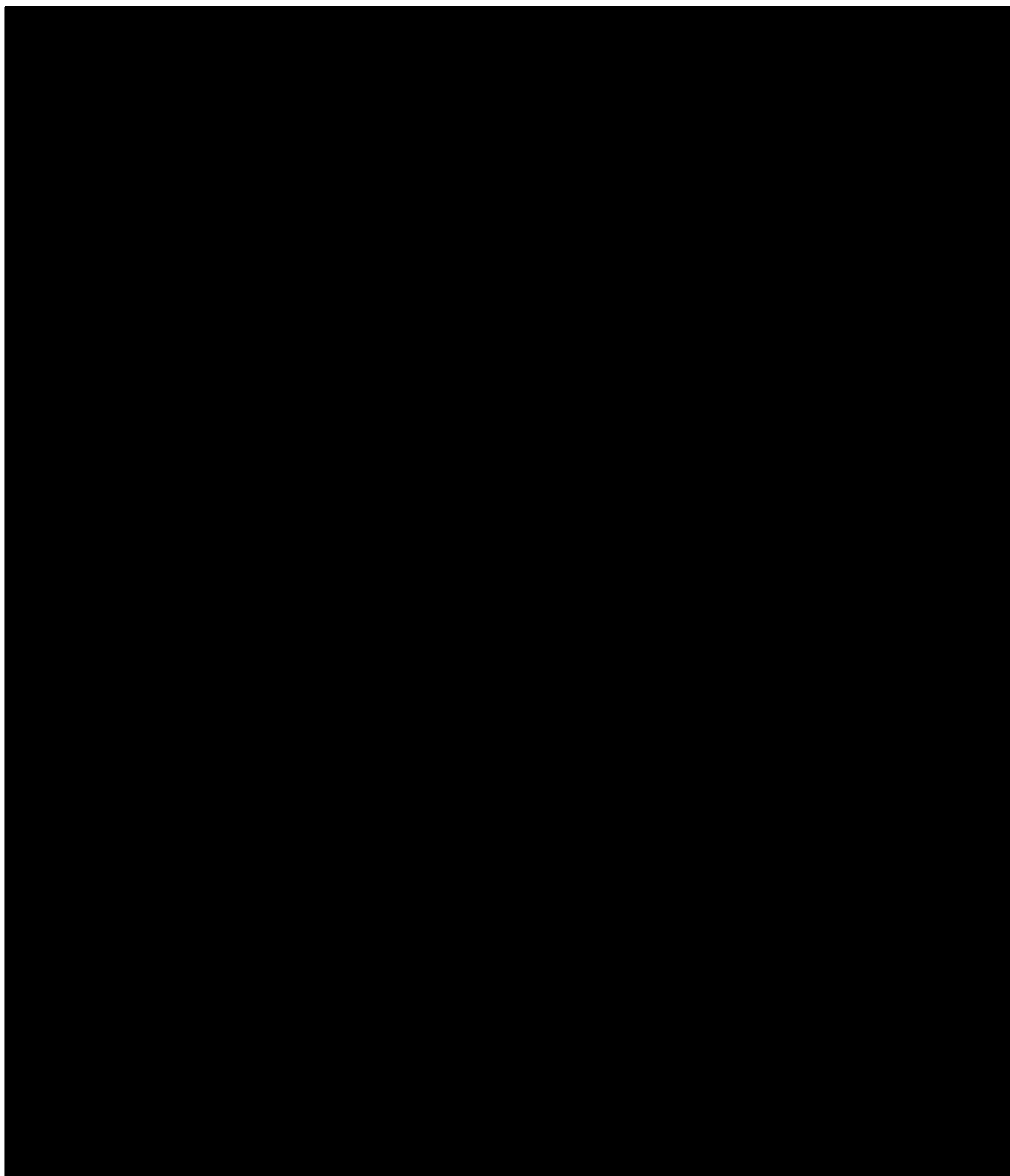


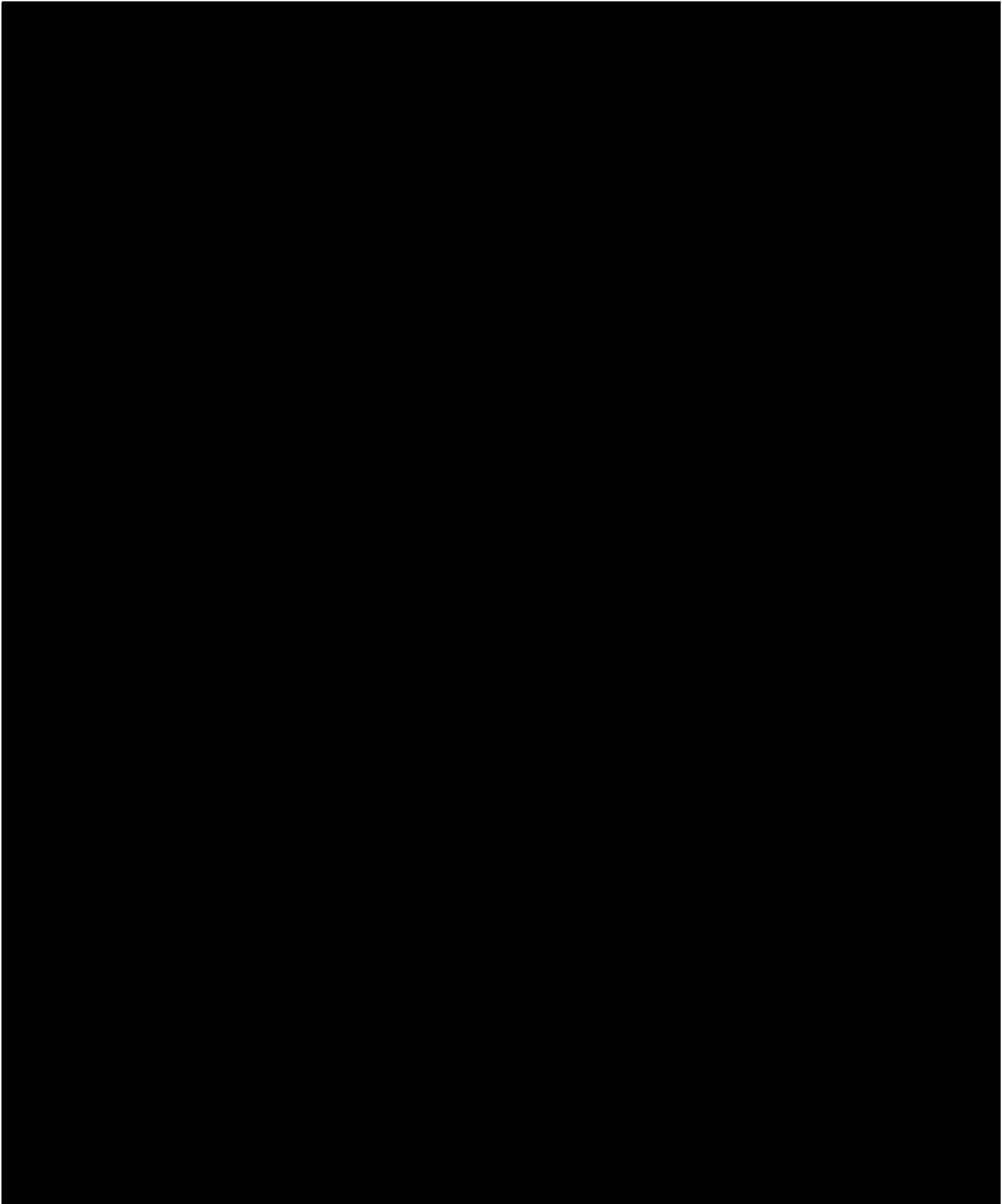


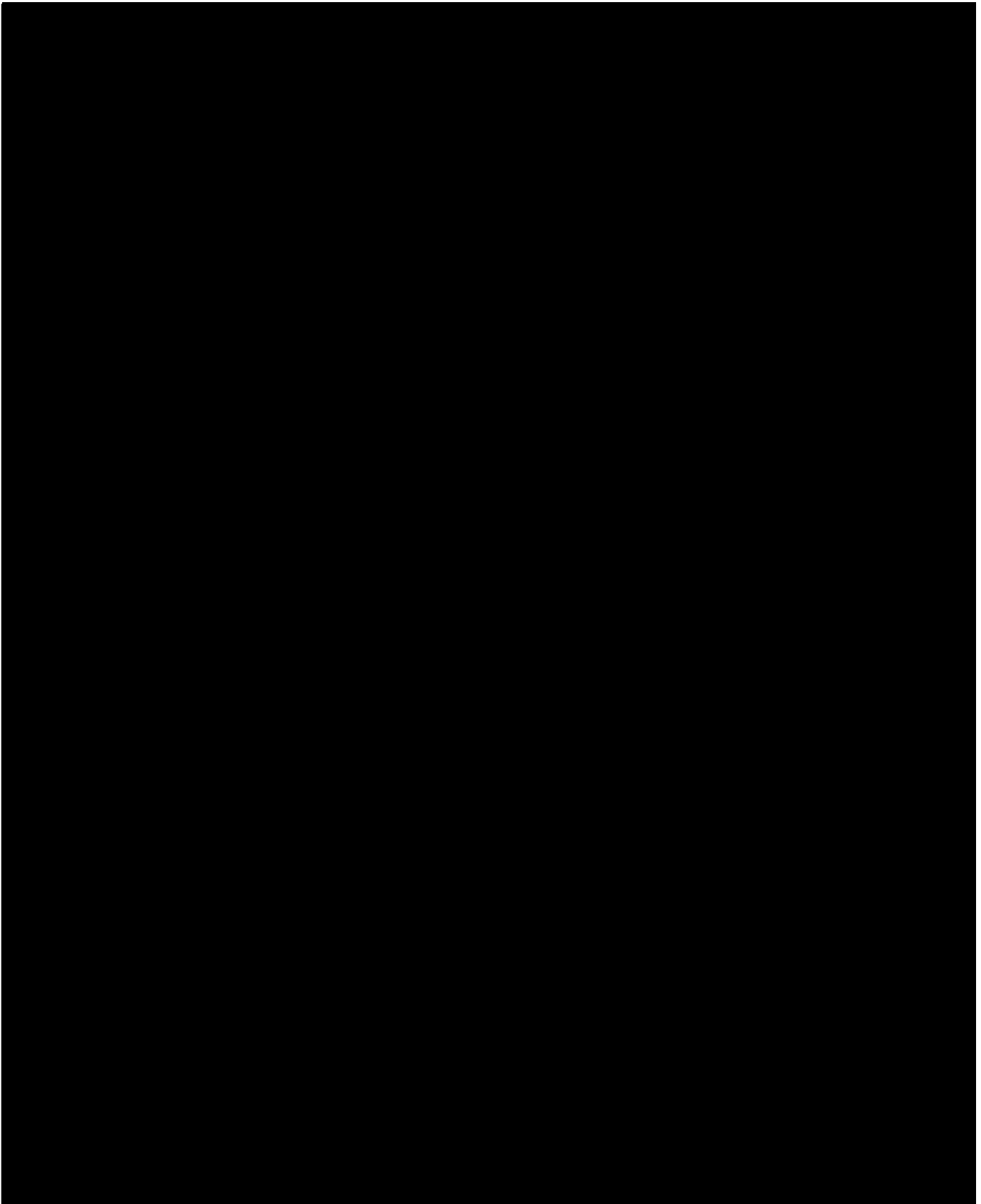


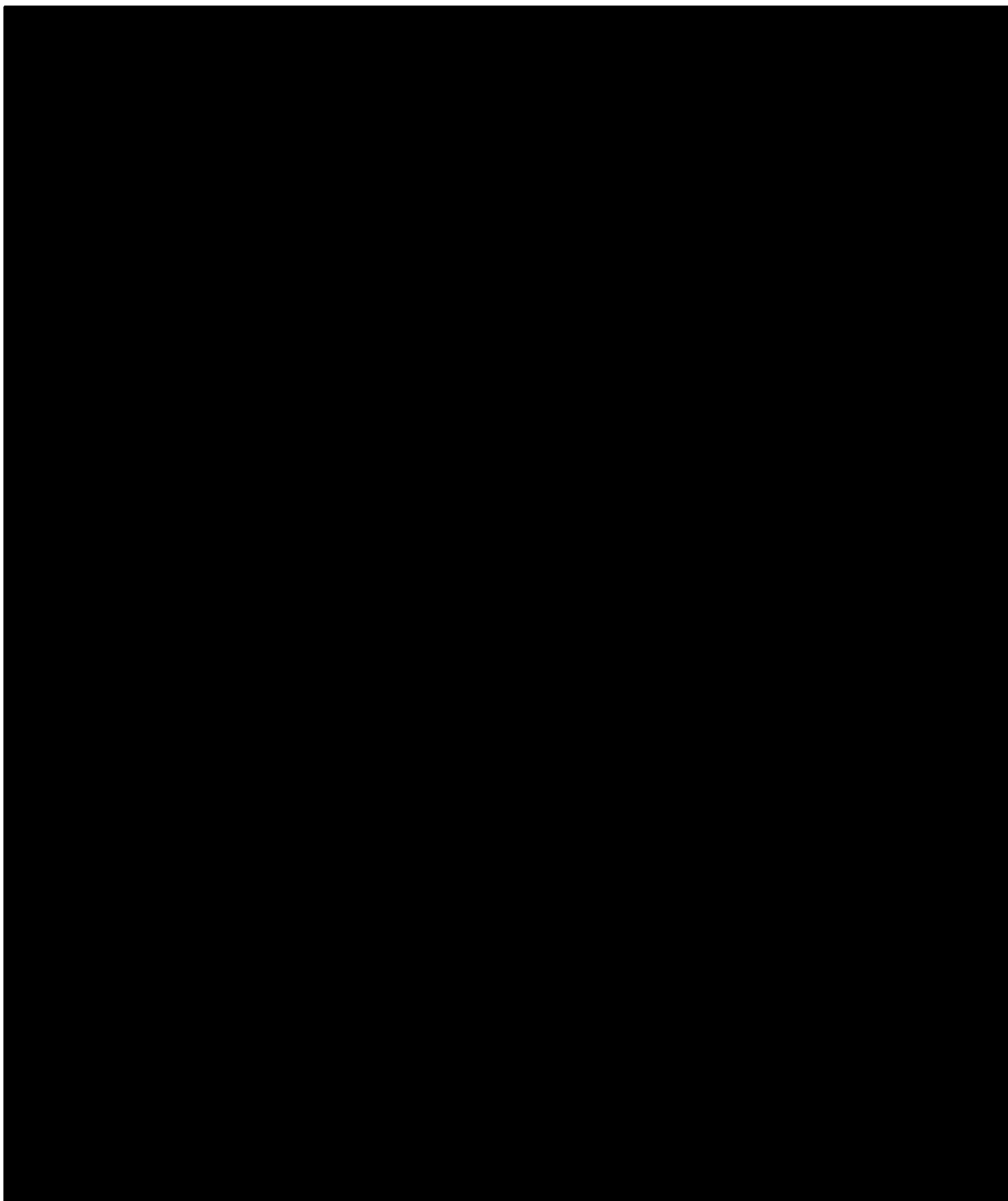






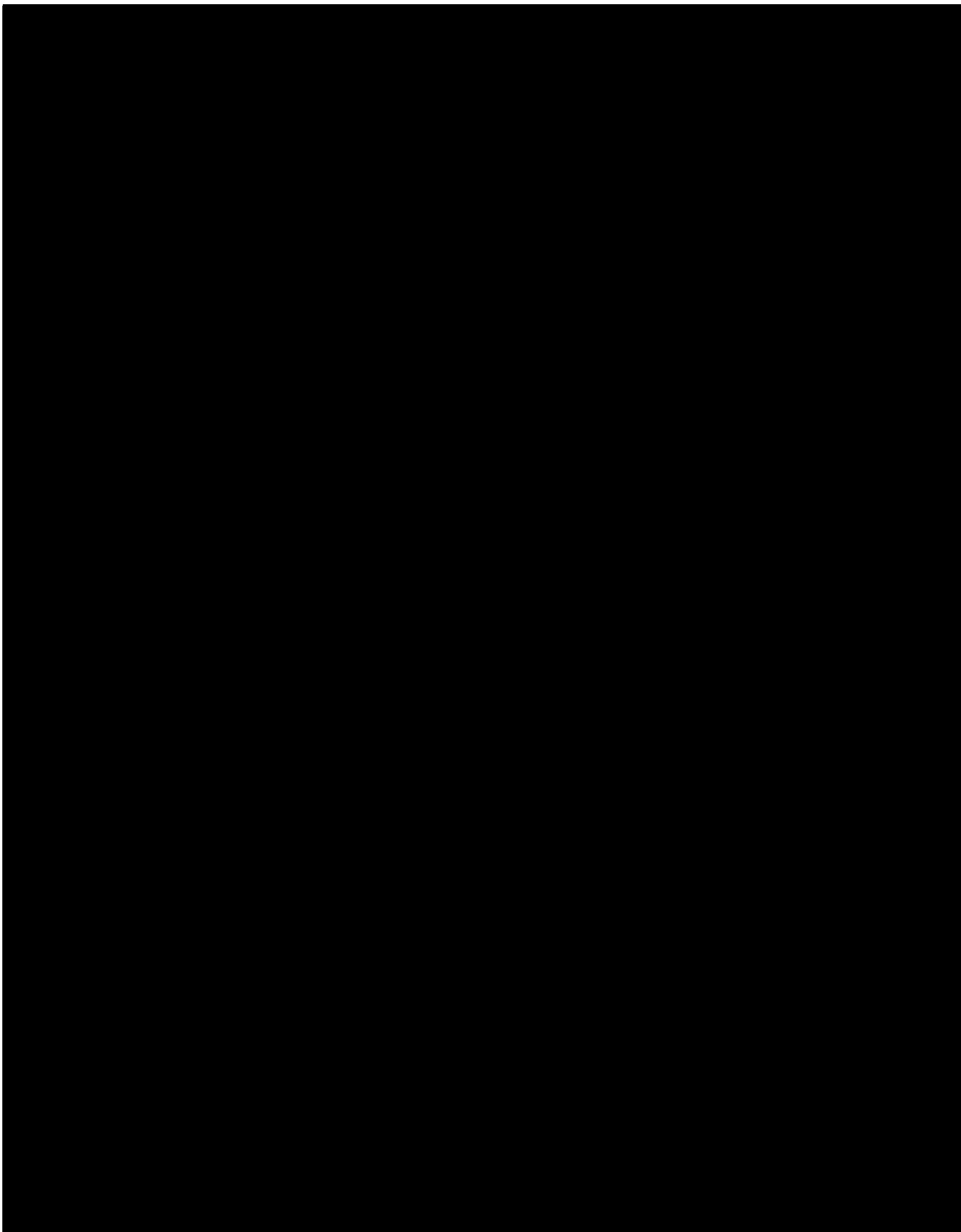




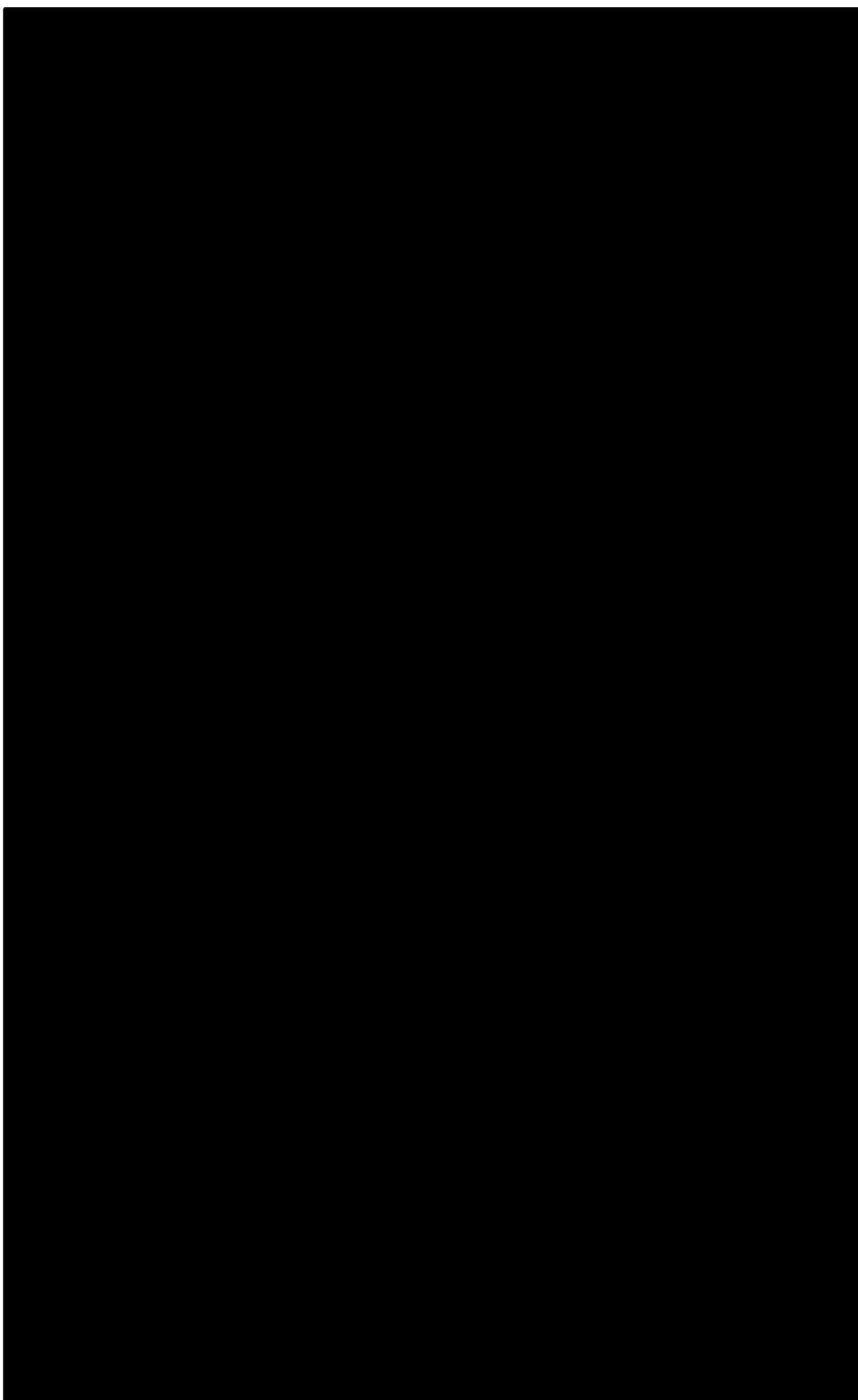


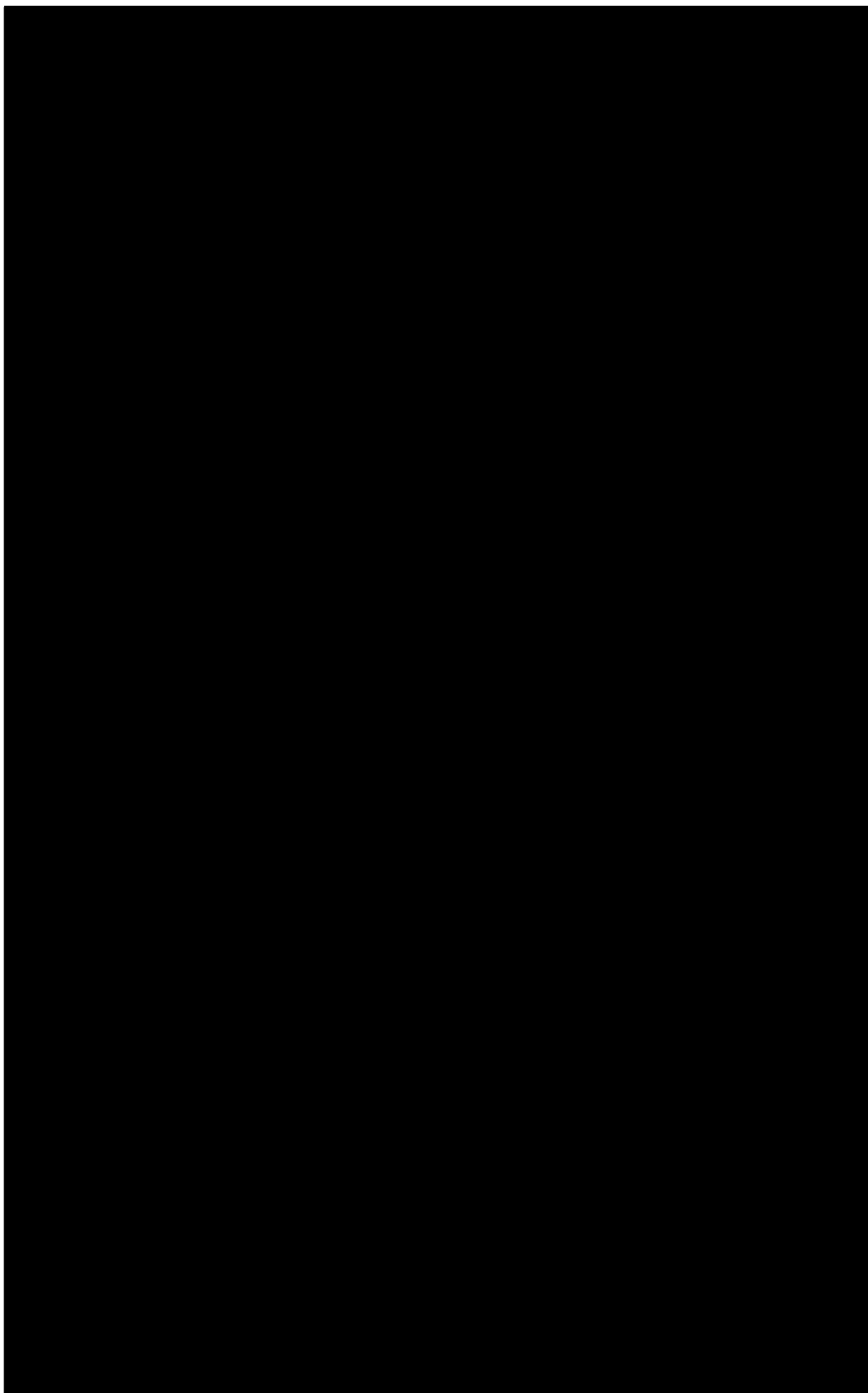


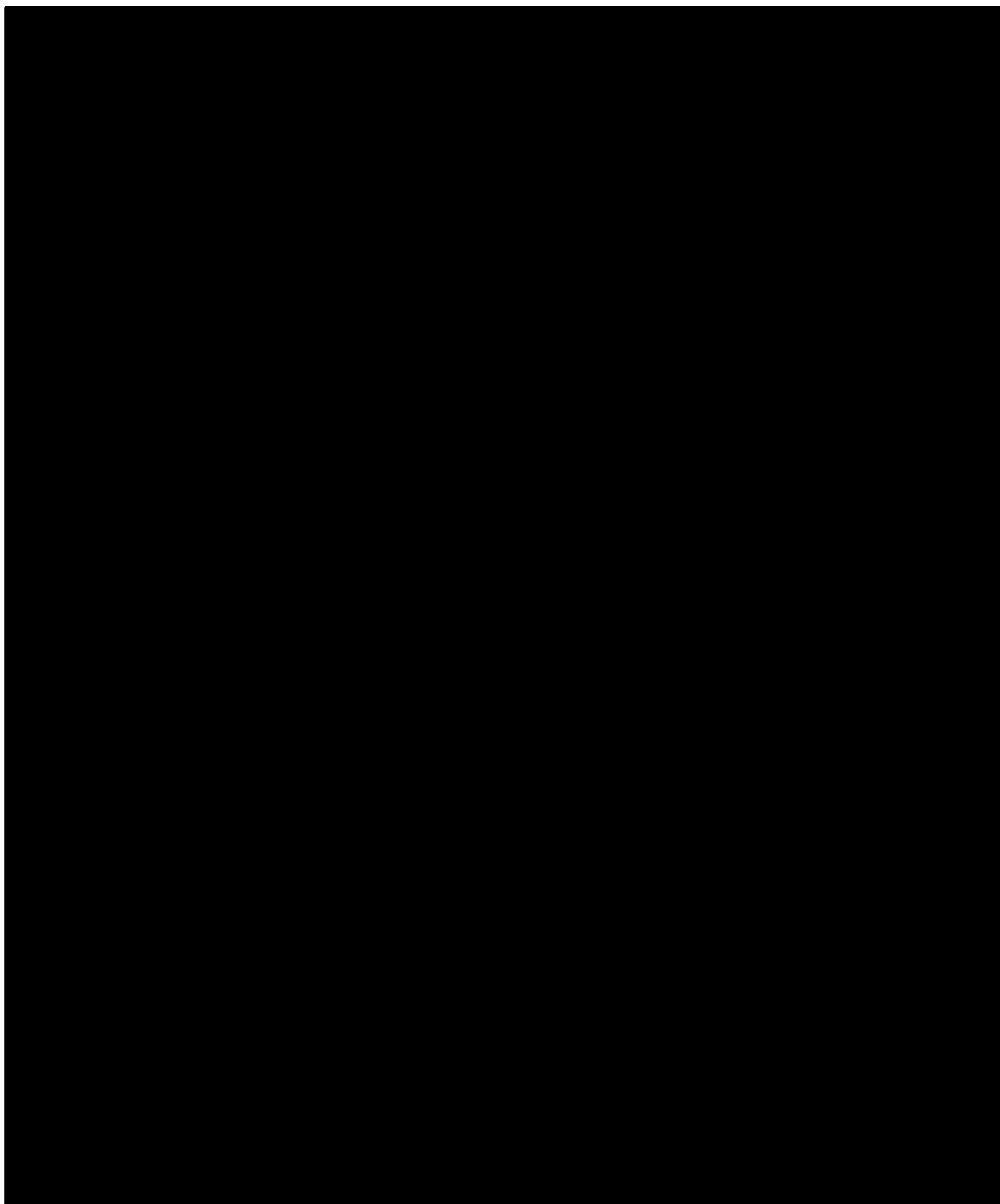


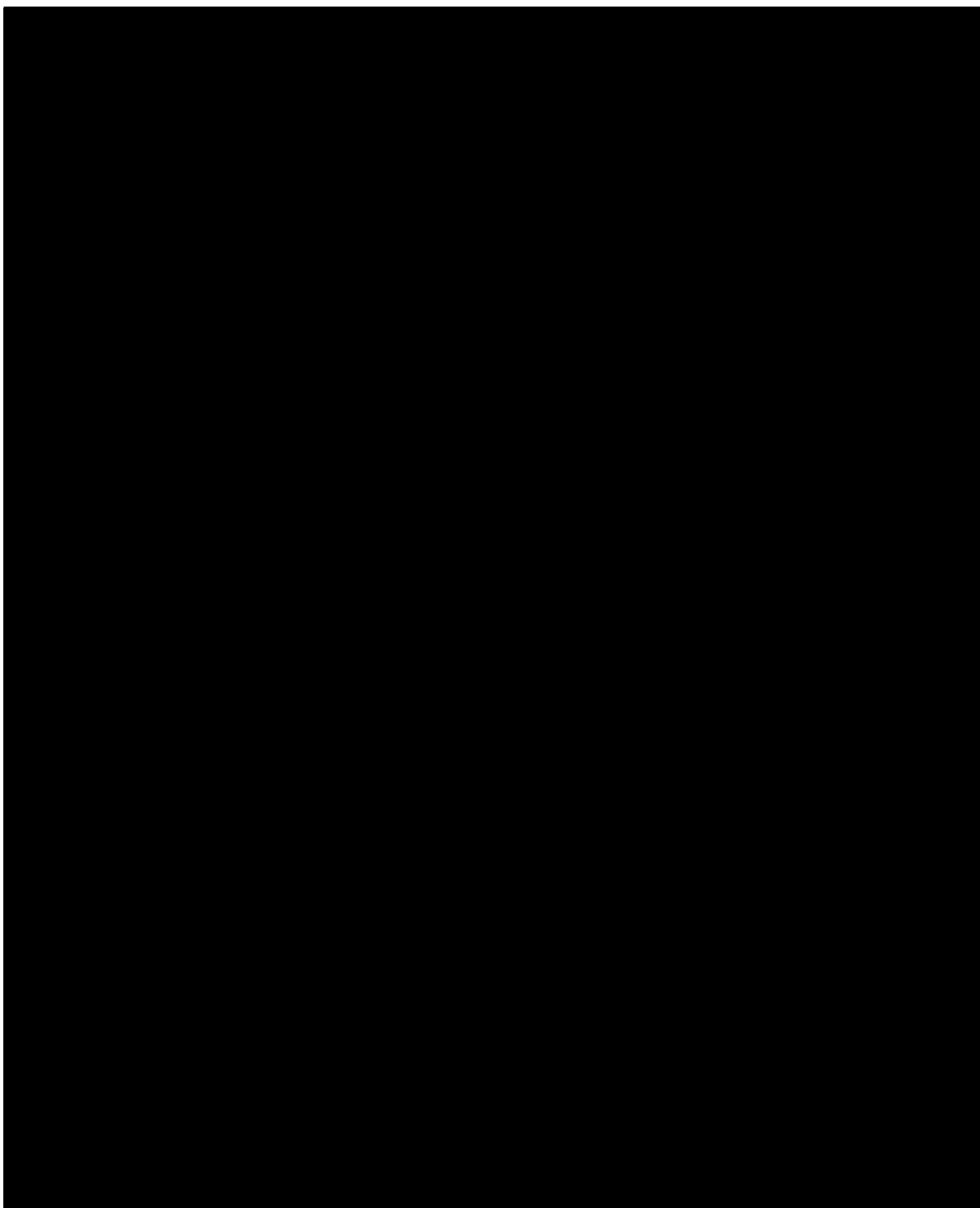


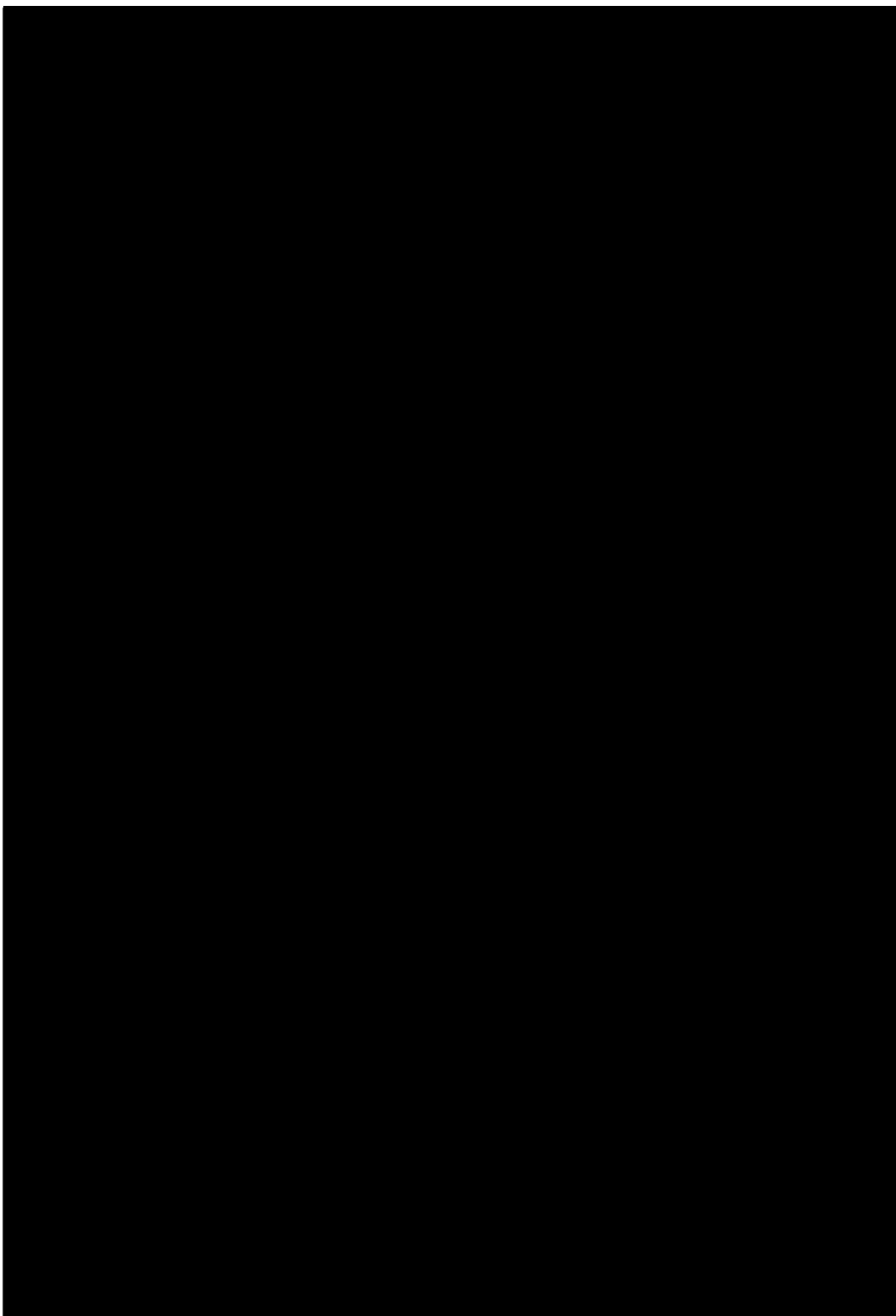


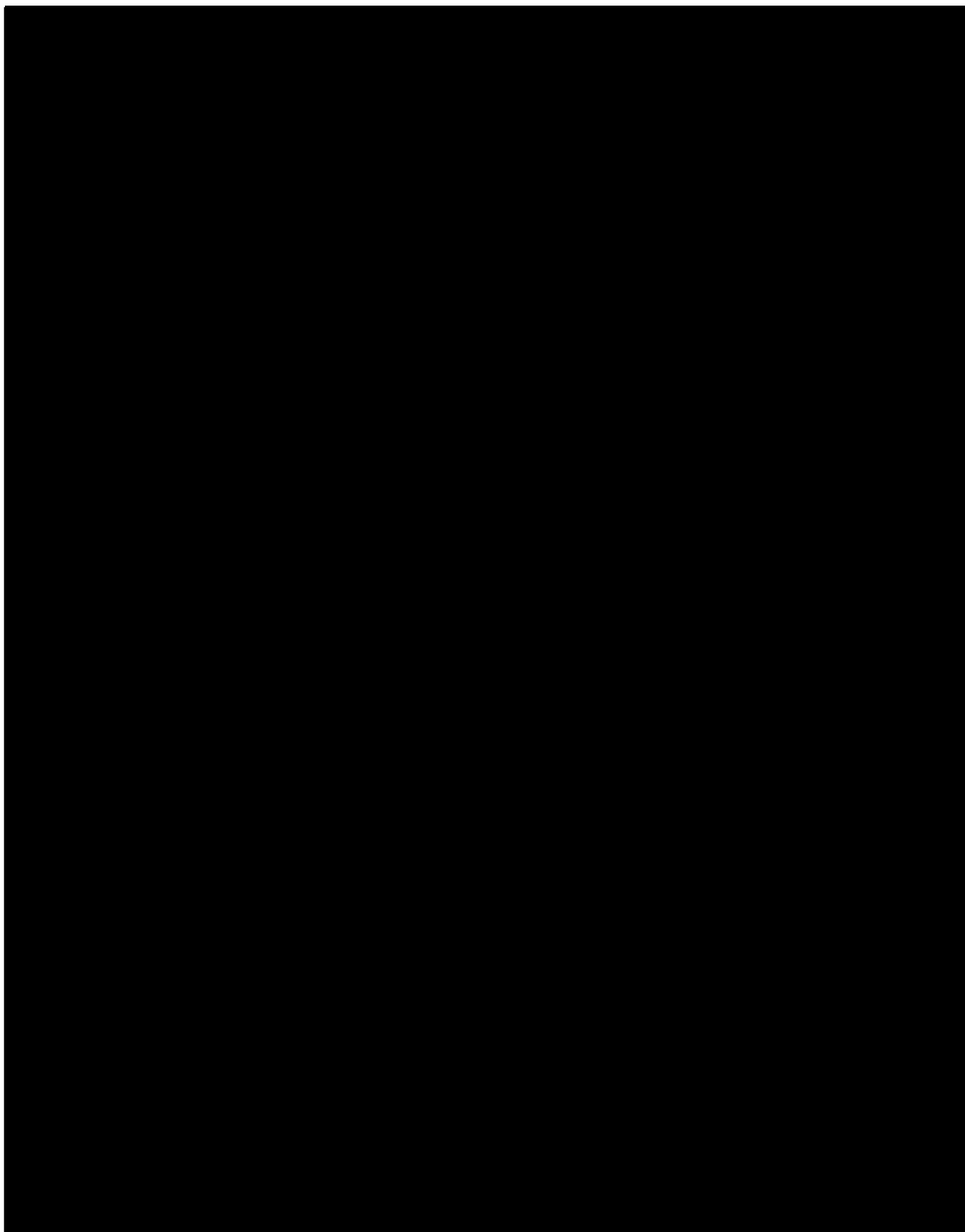


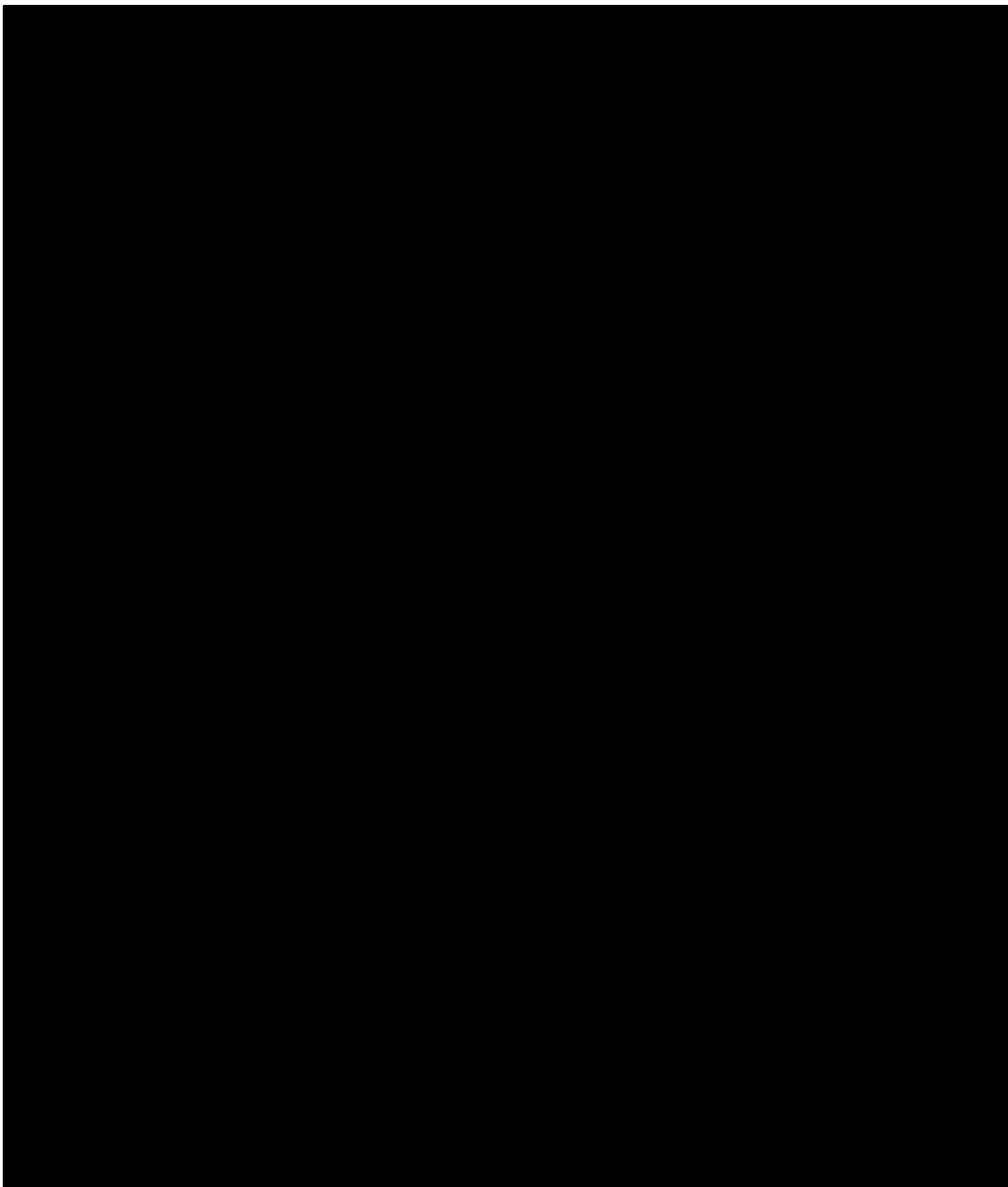


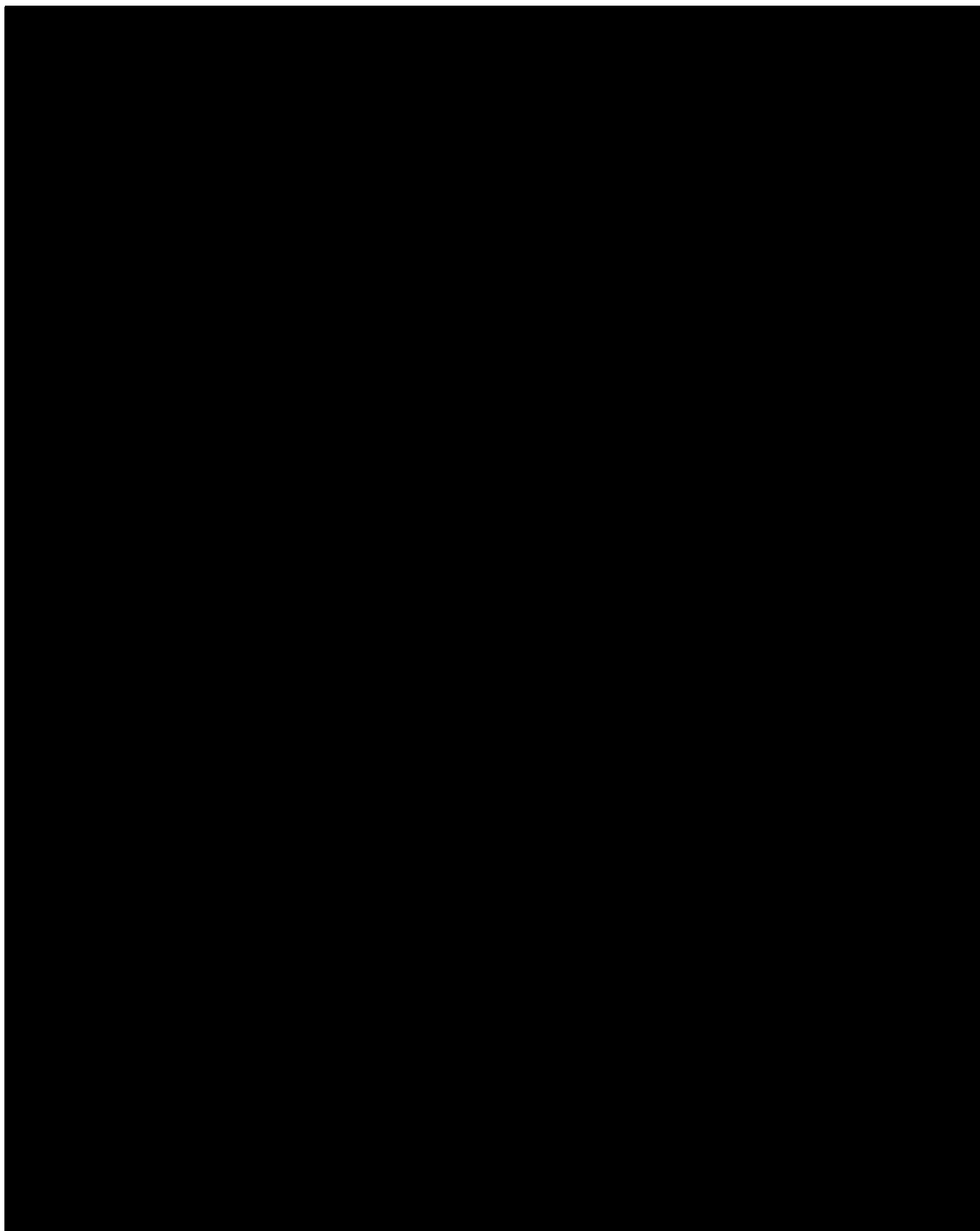




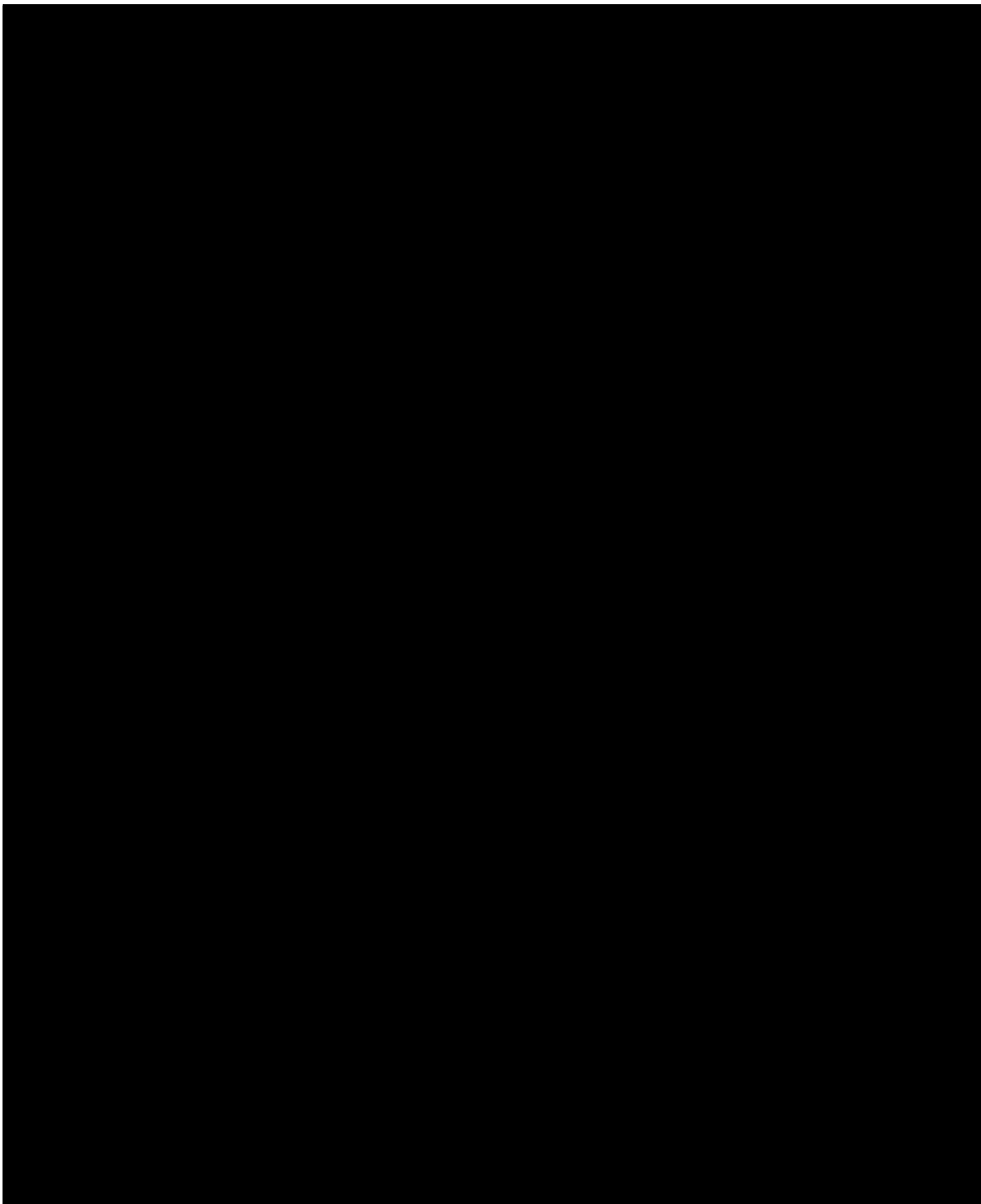


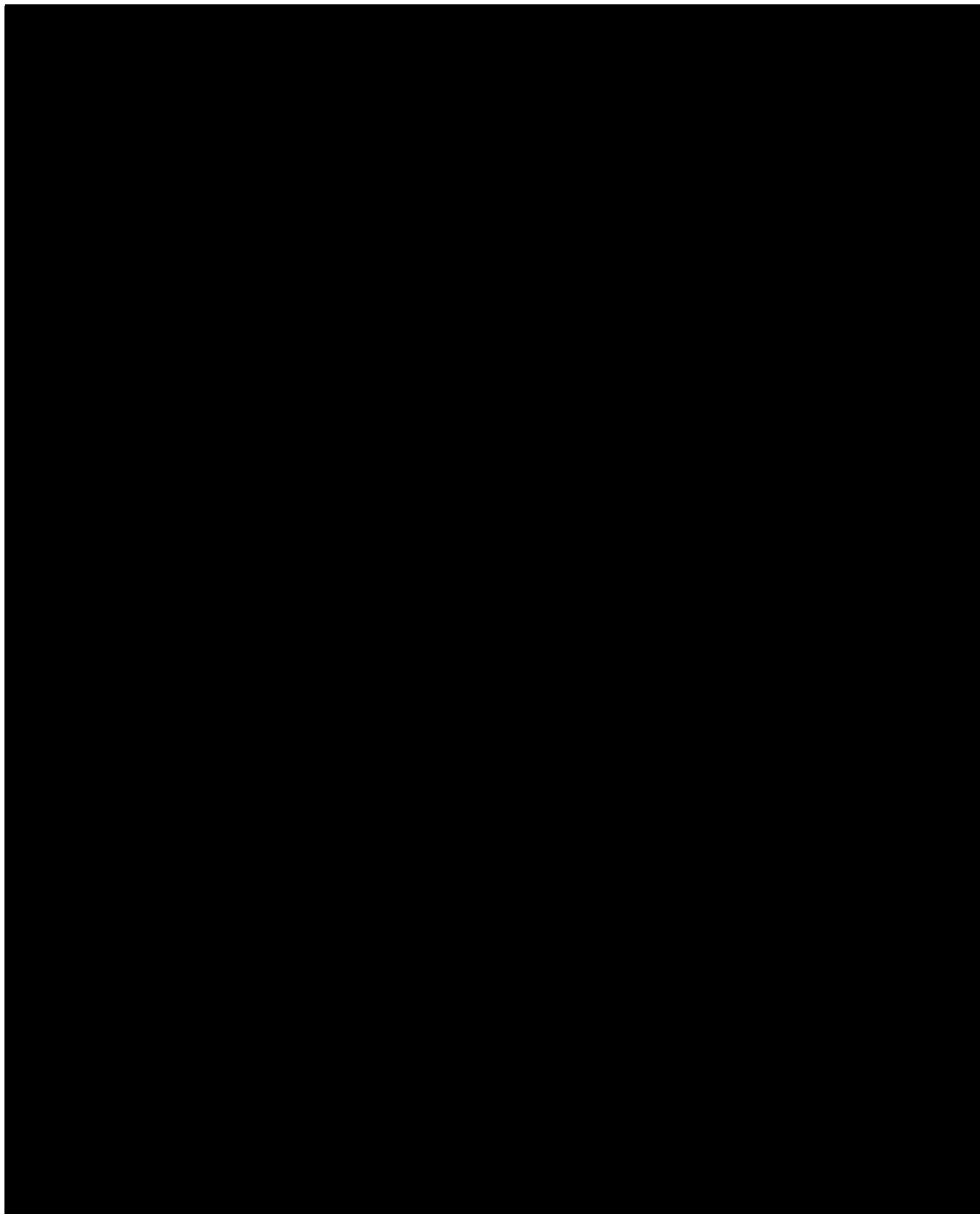


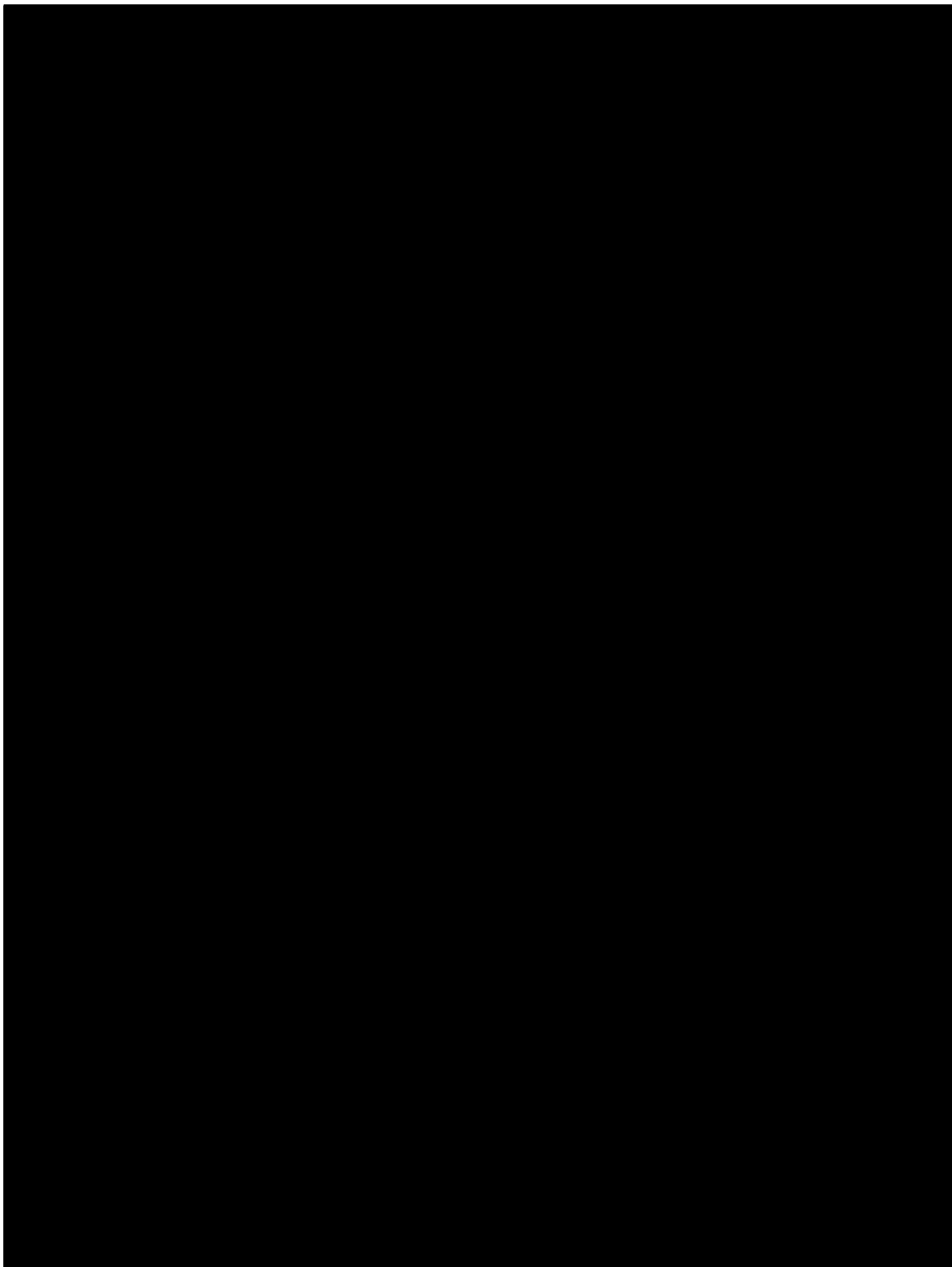


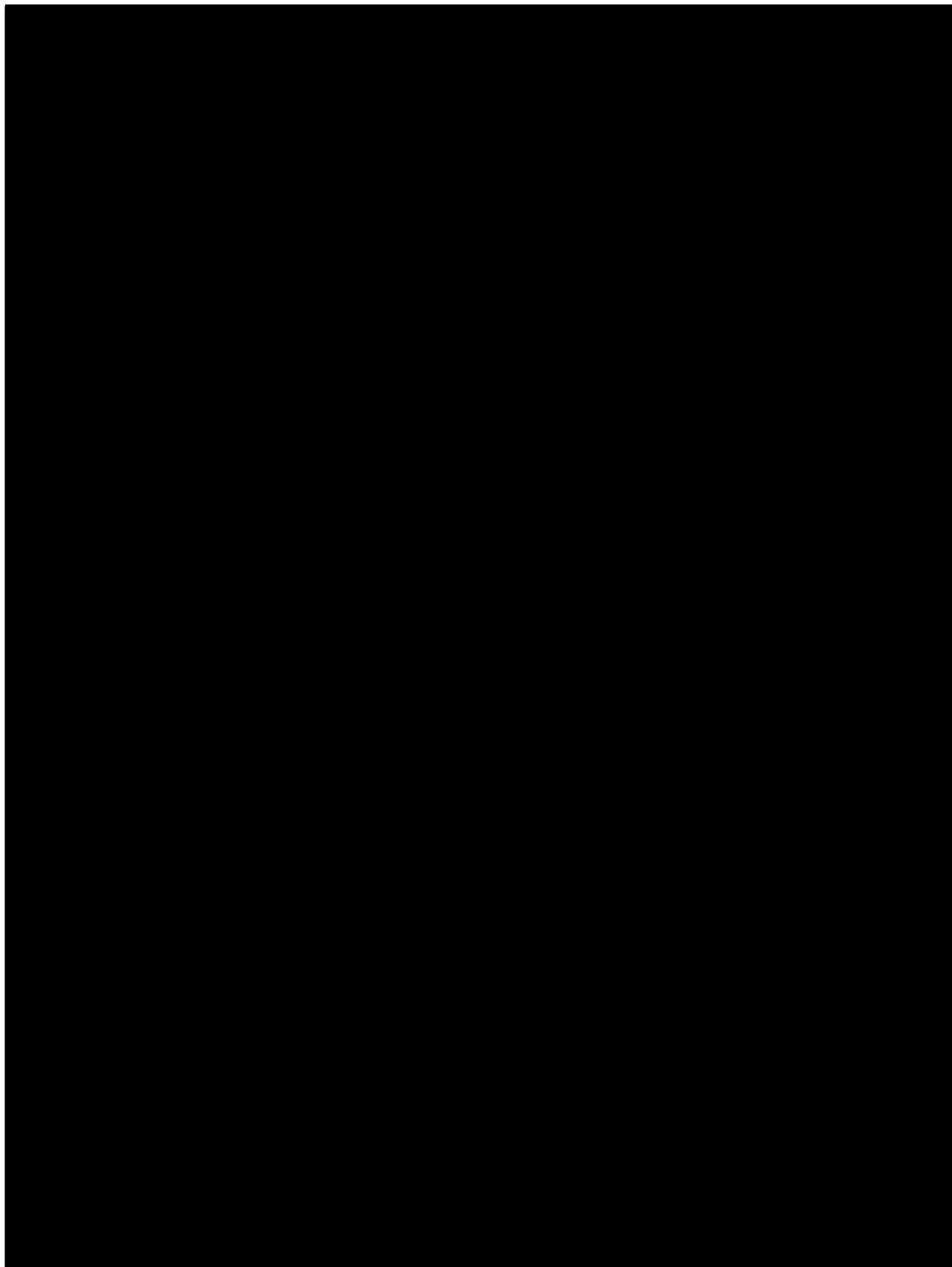


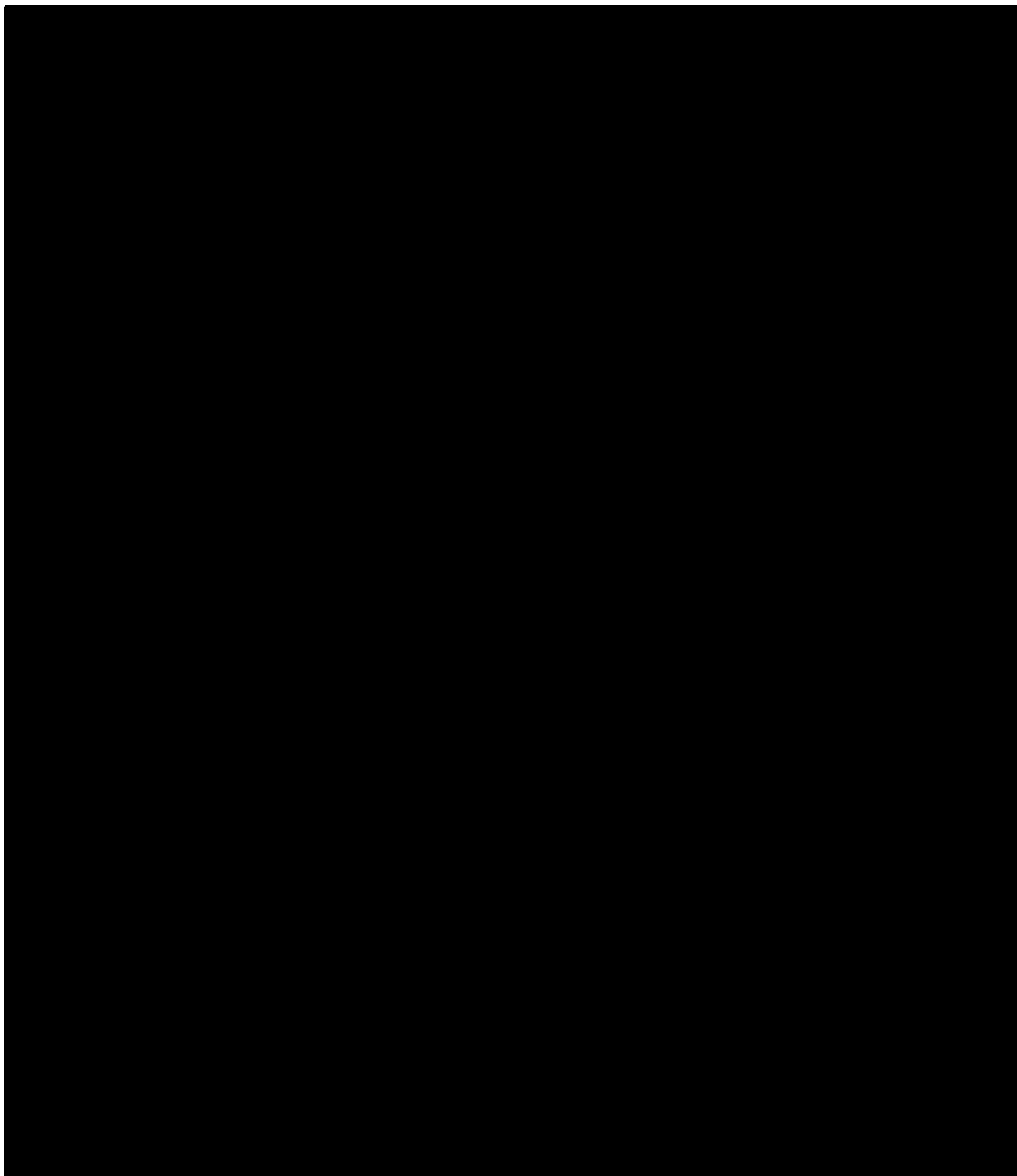










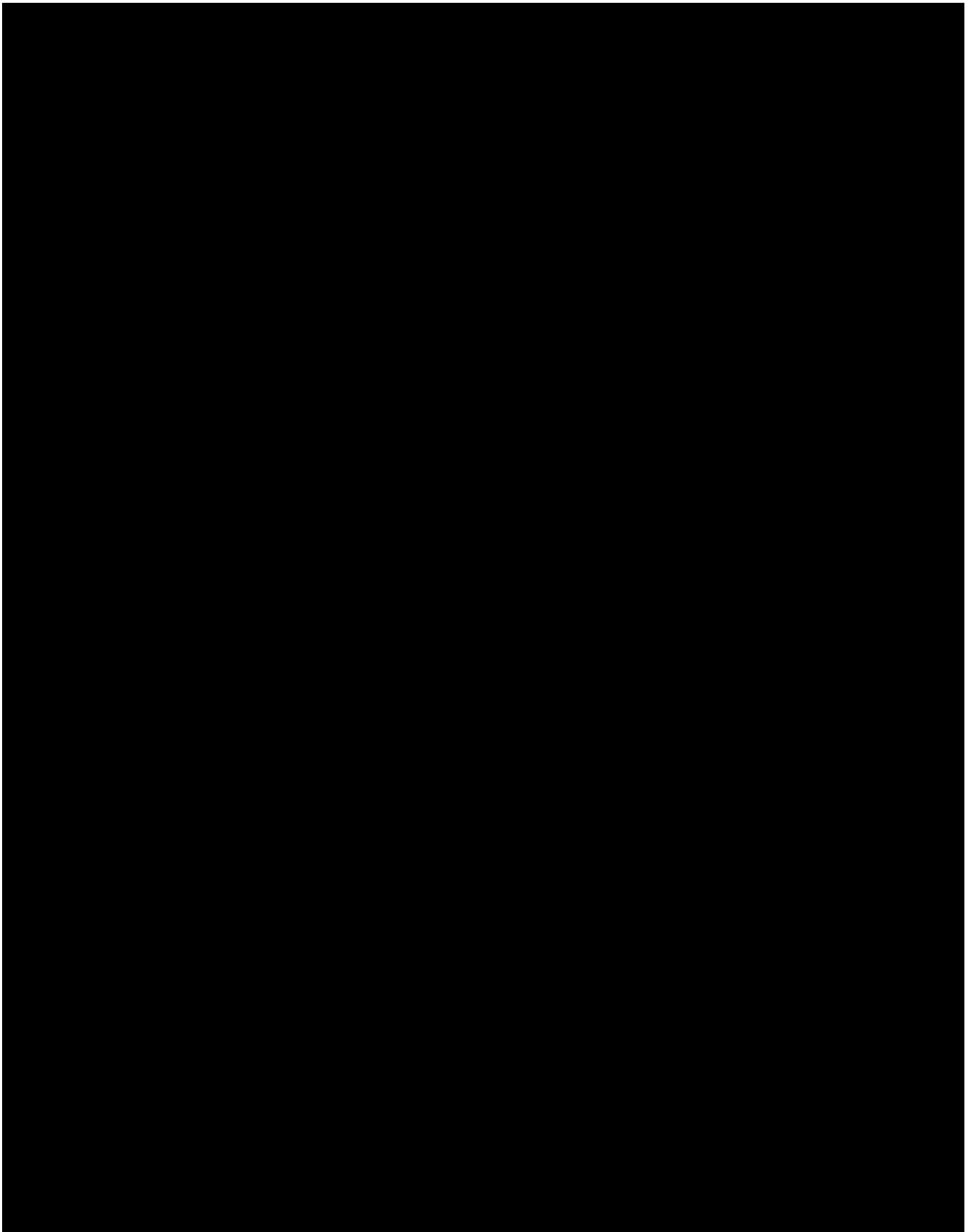


# **EXHIBIT 4**

## **FILED UNDER SEAL**

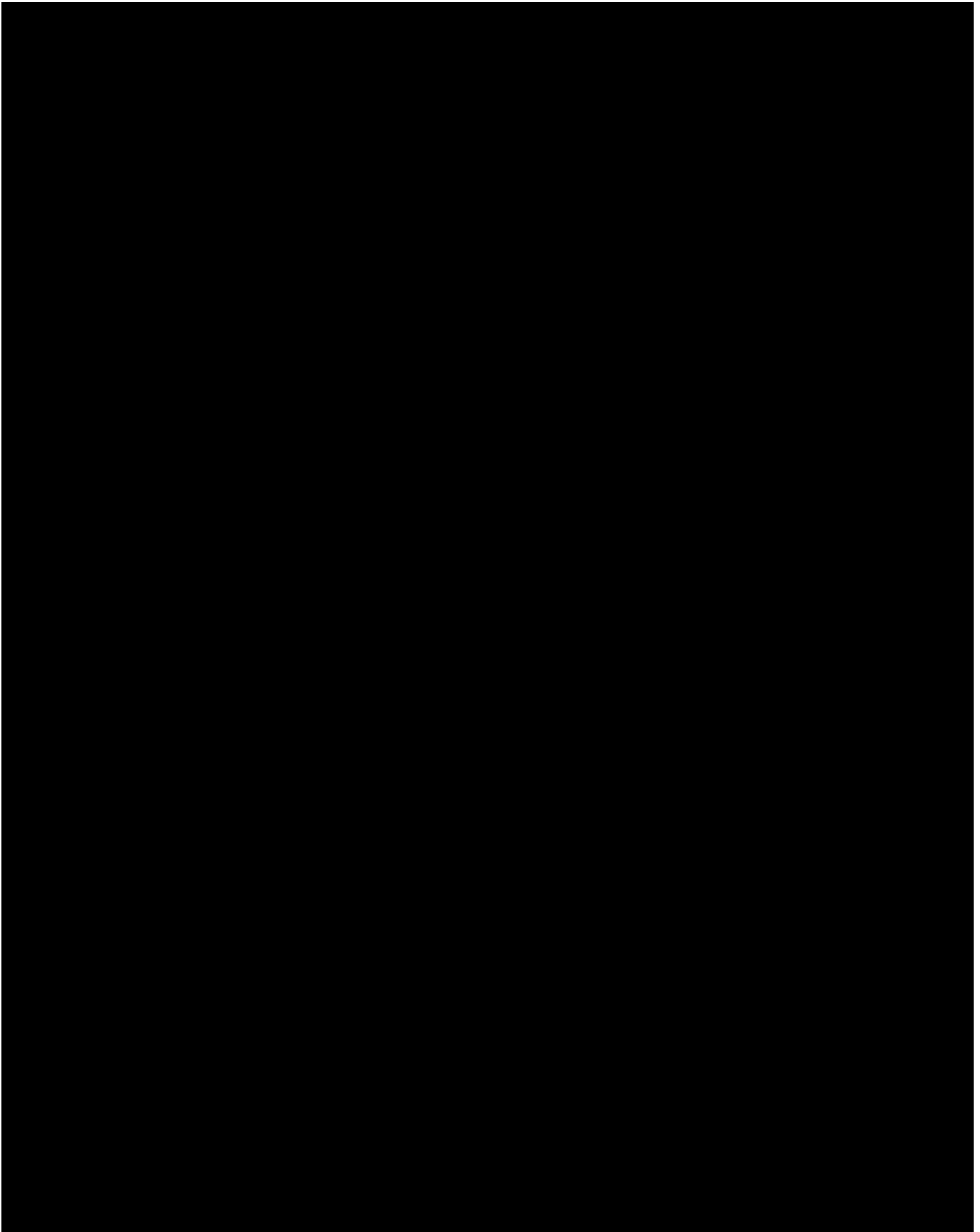


**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

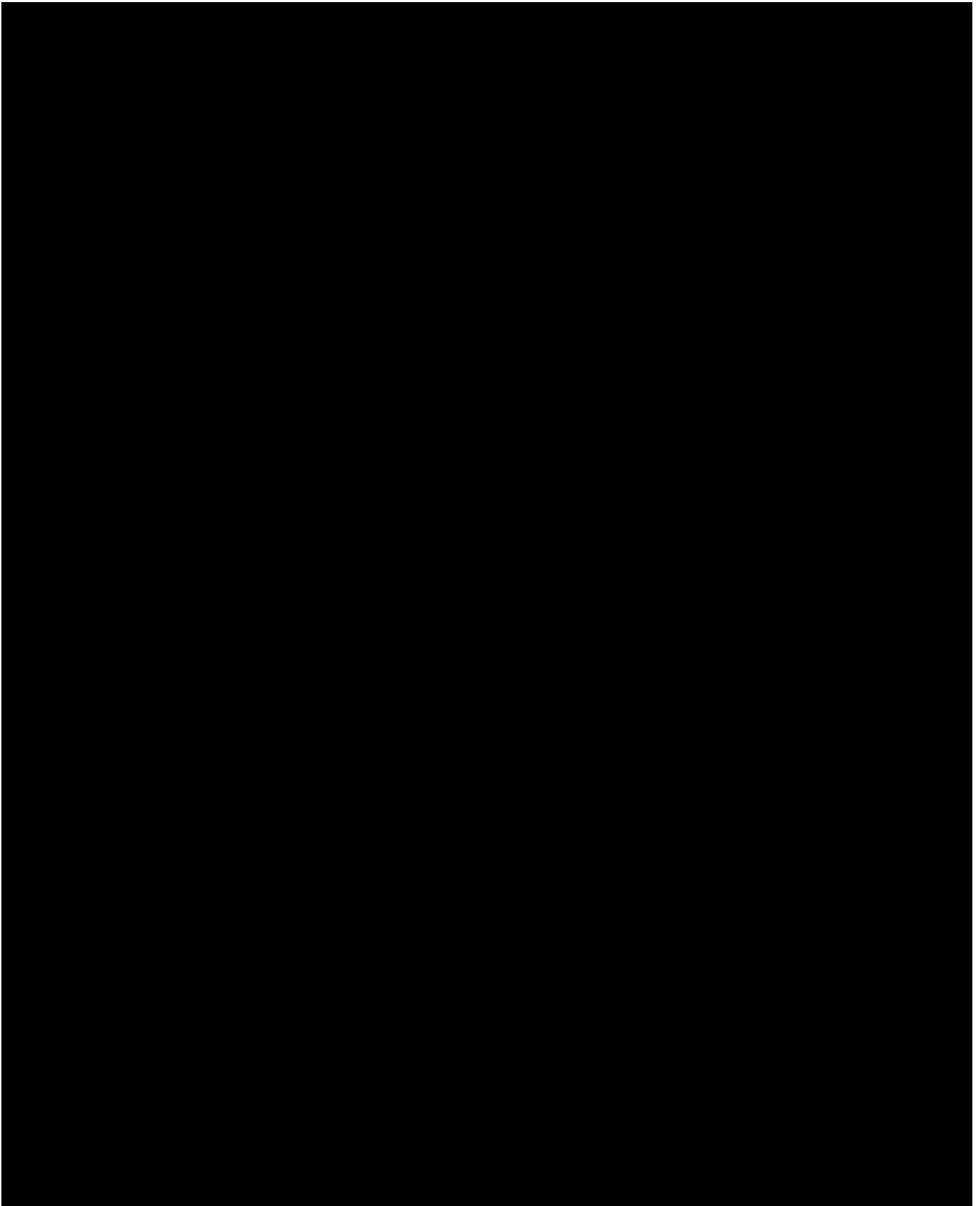




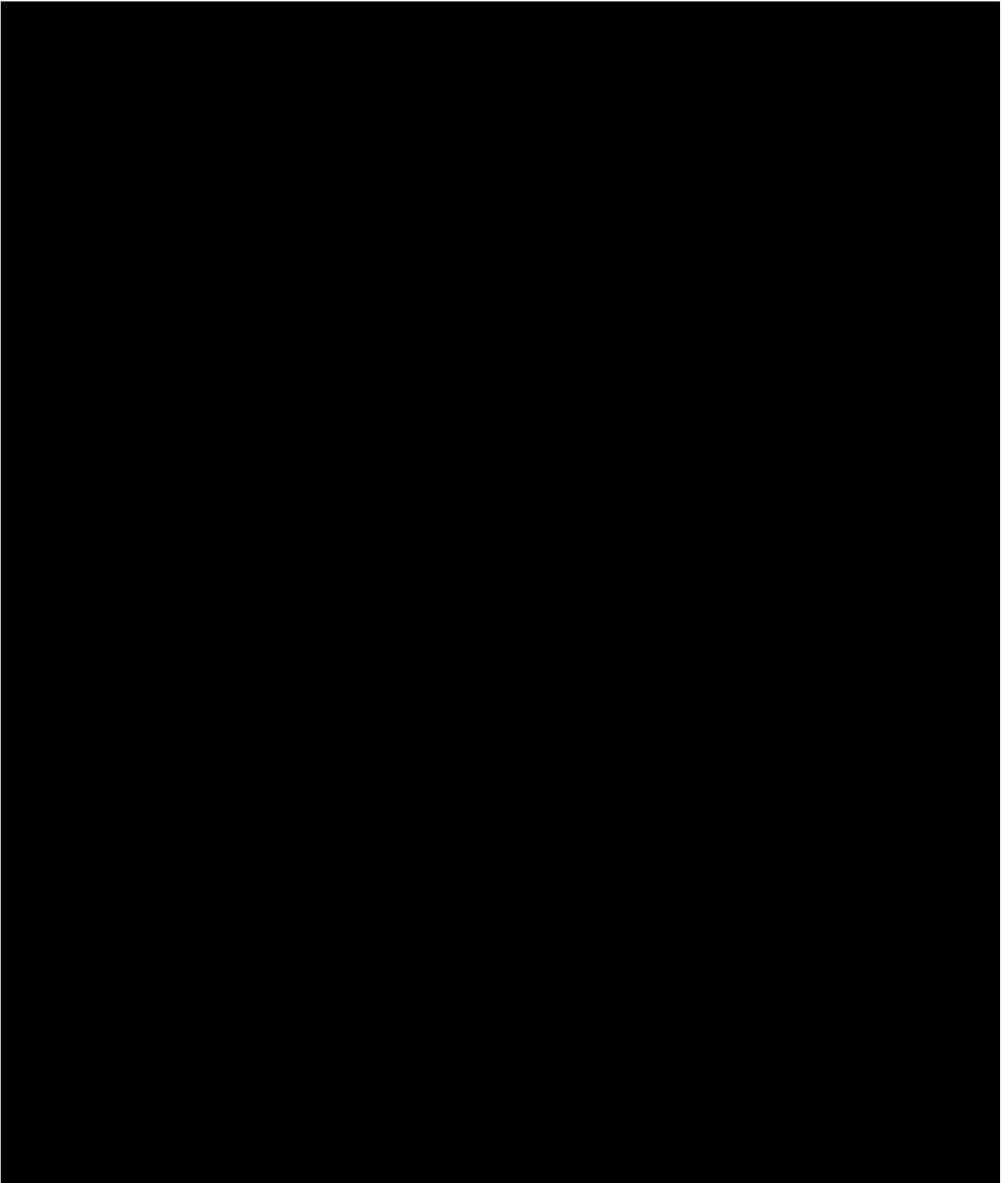
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**



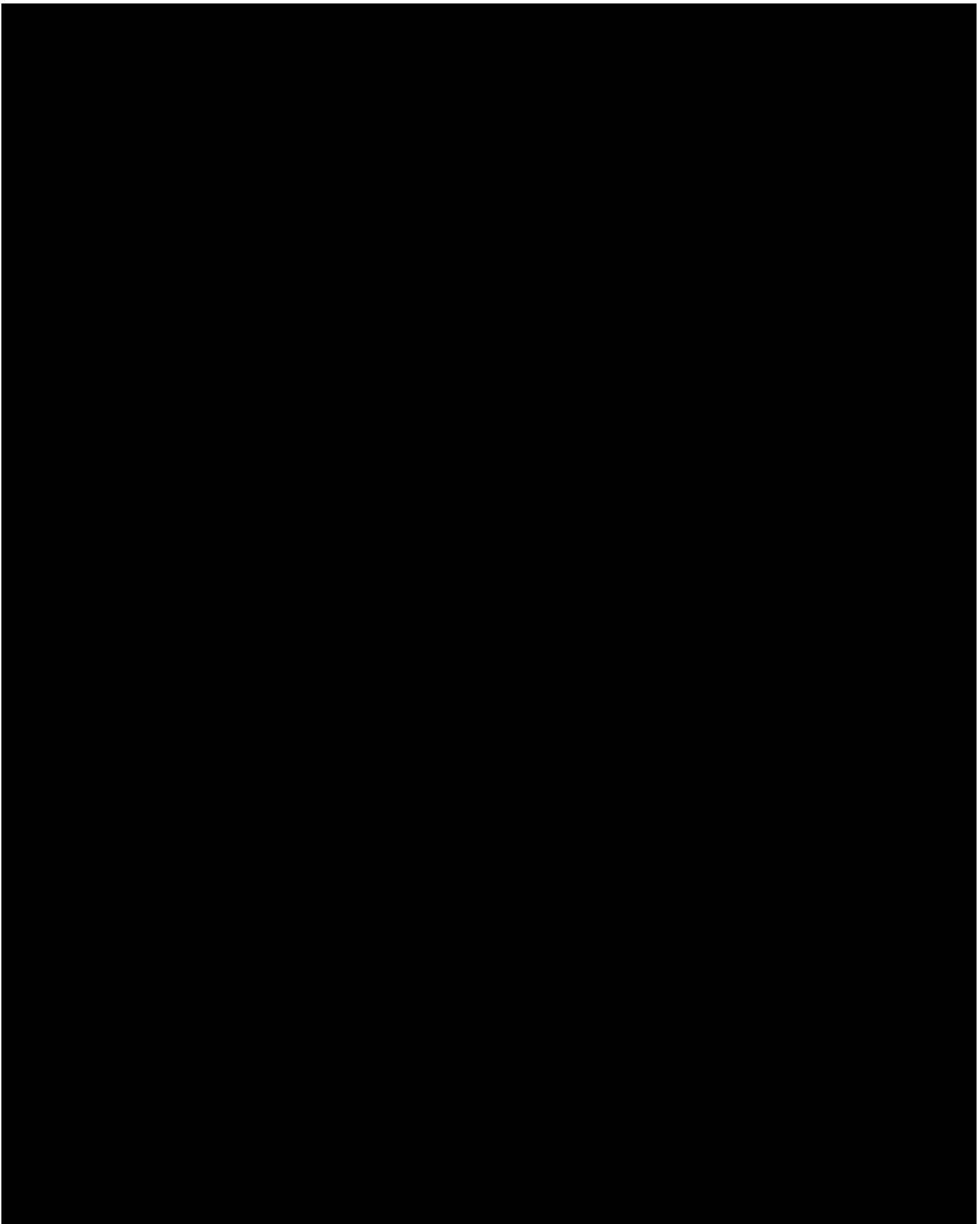
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**



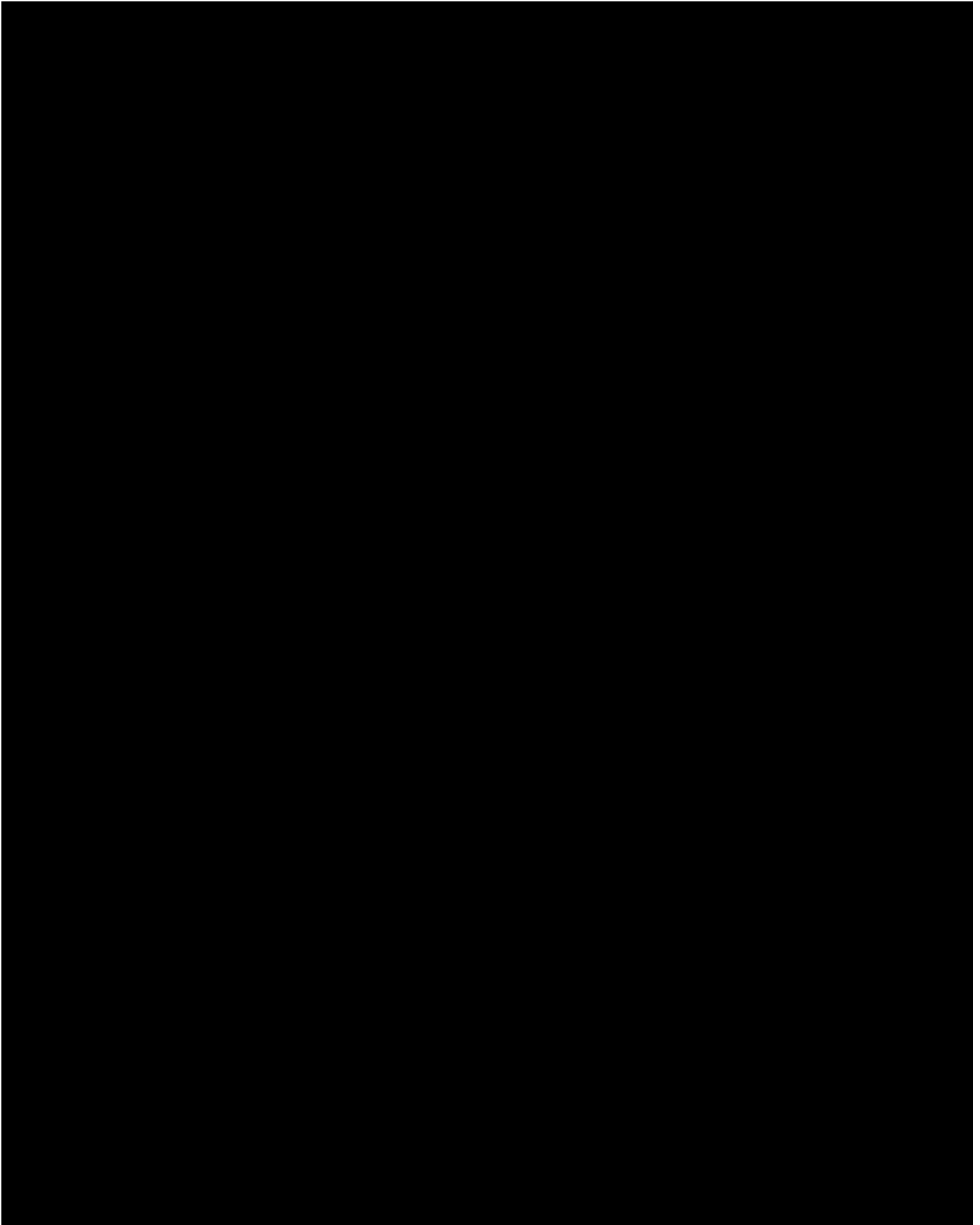
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**



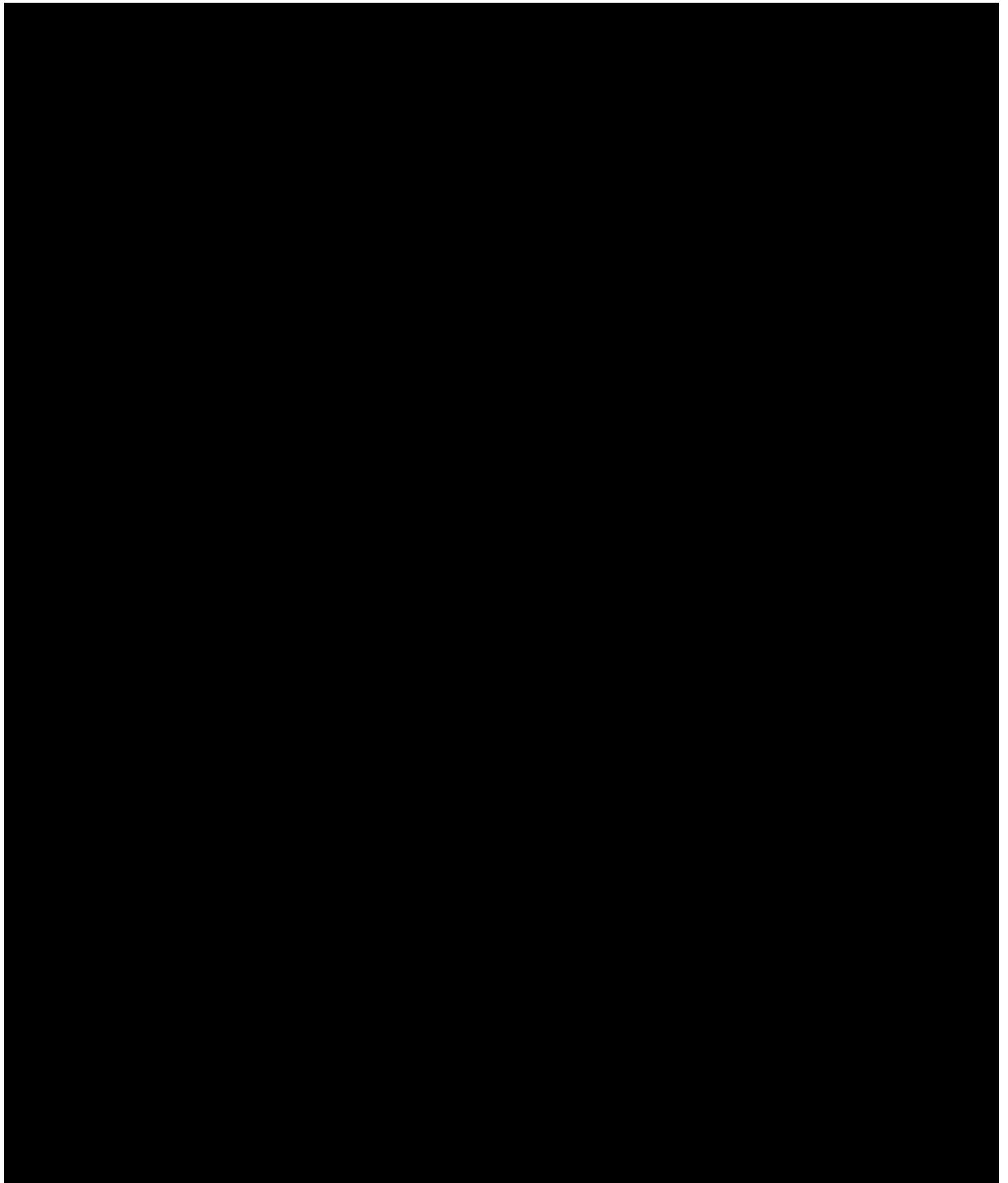
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**



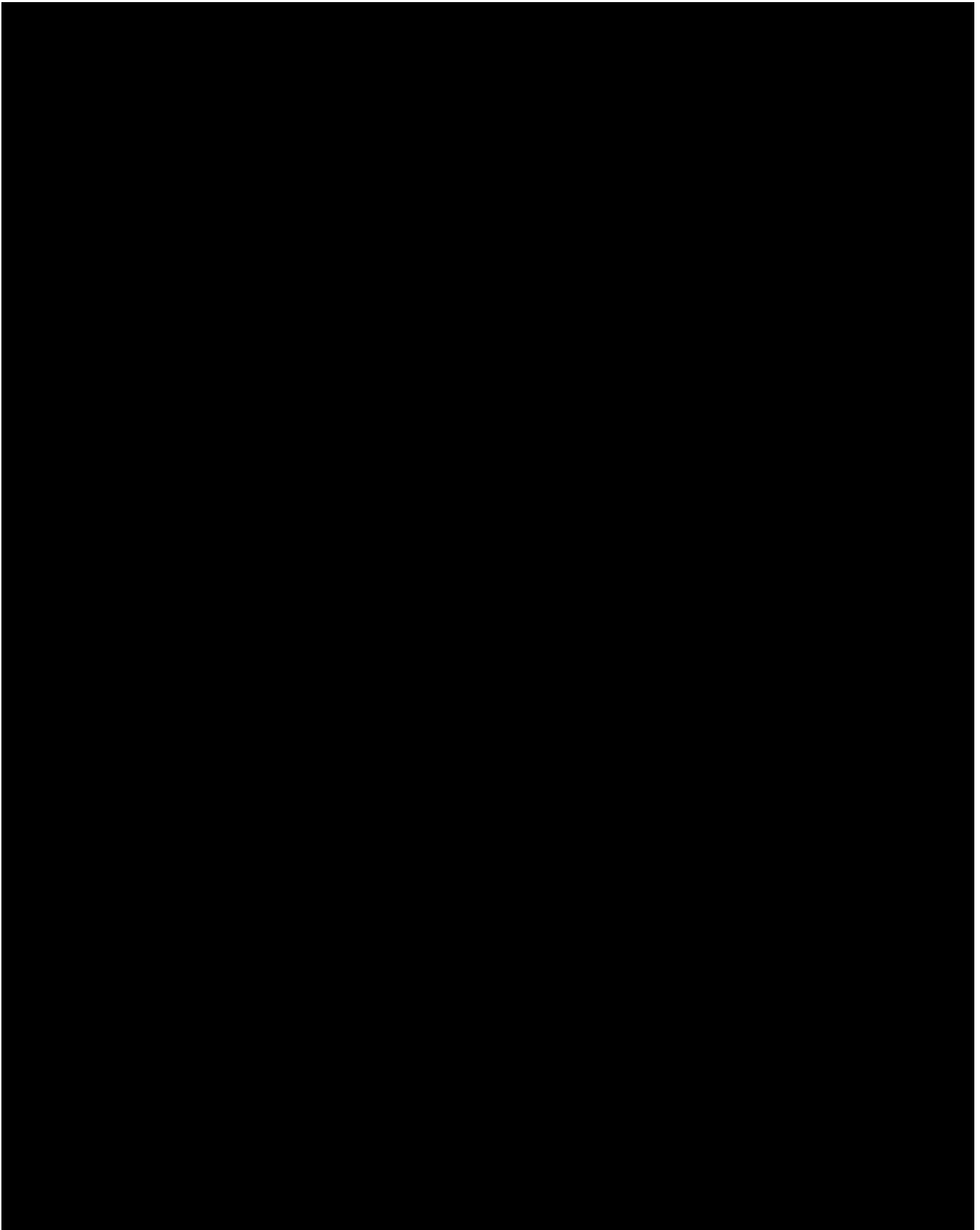
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**



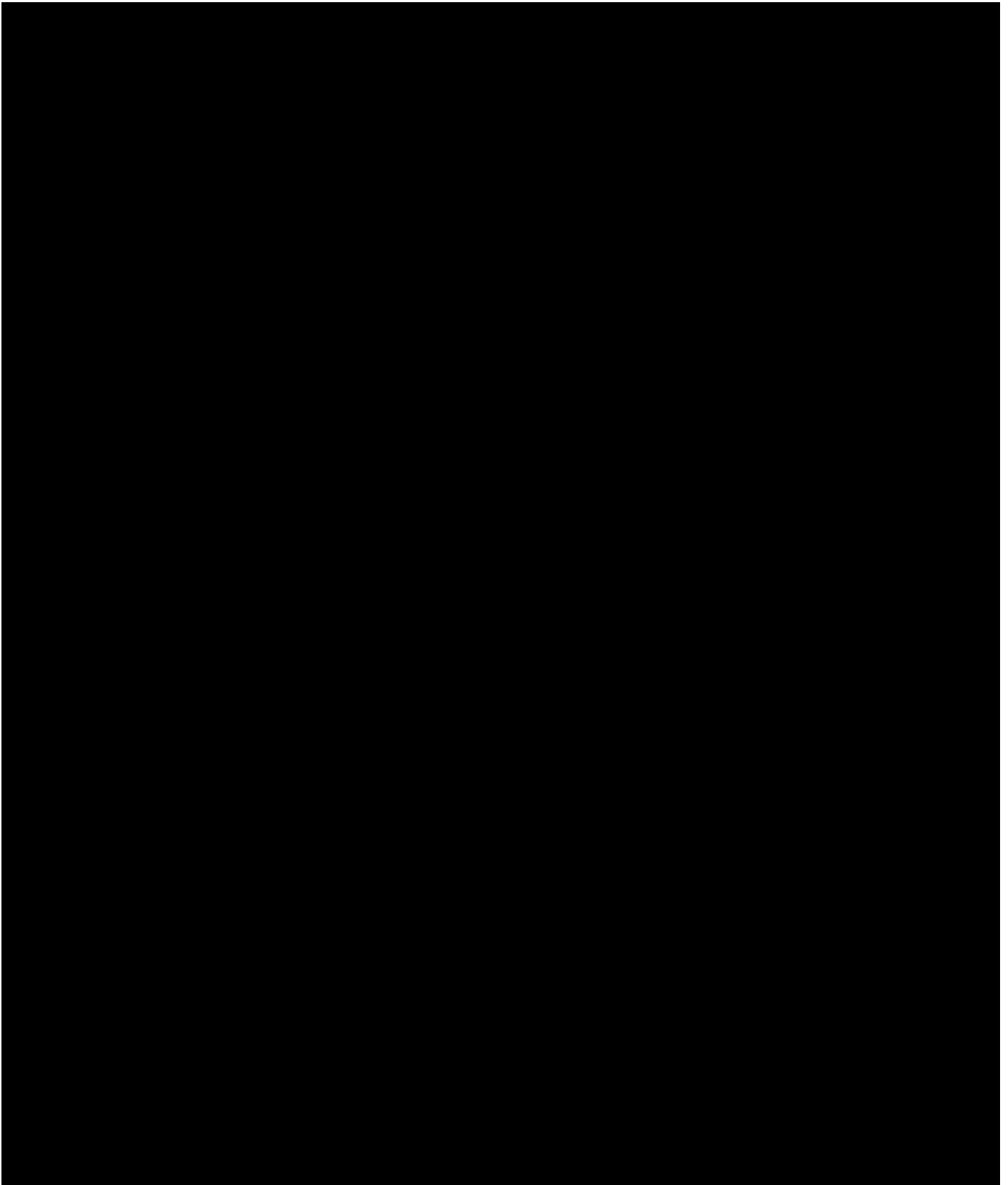
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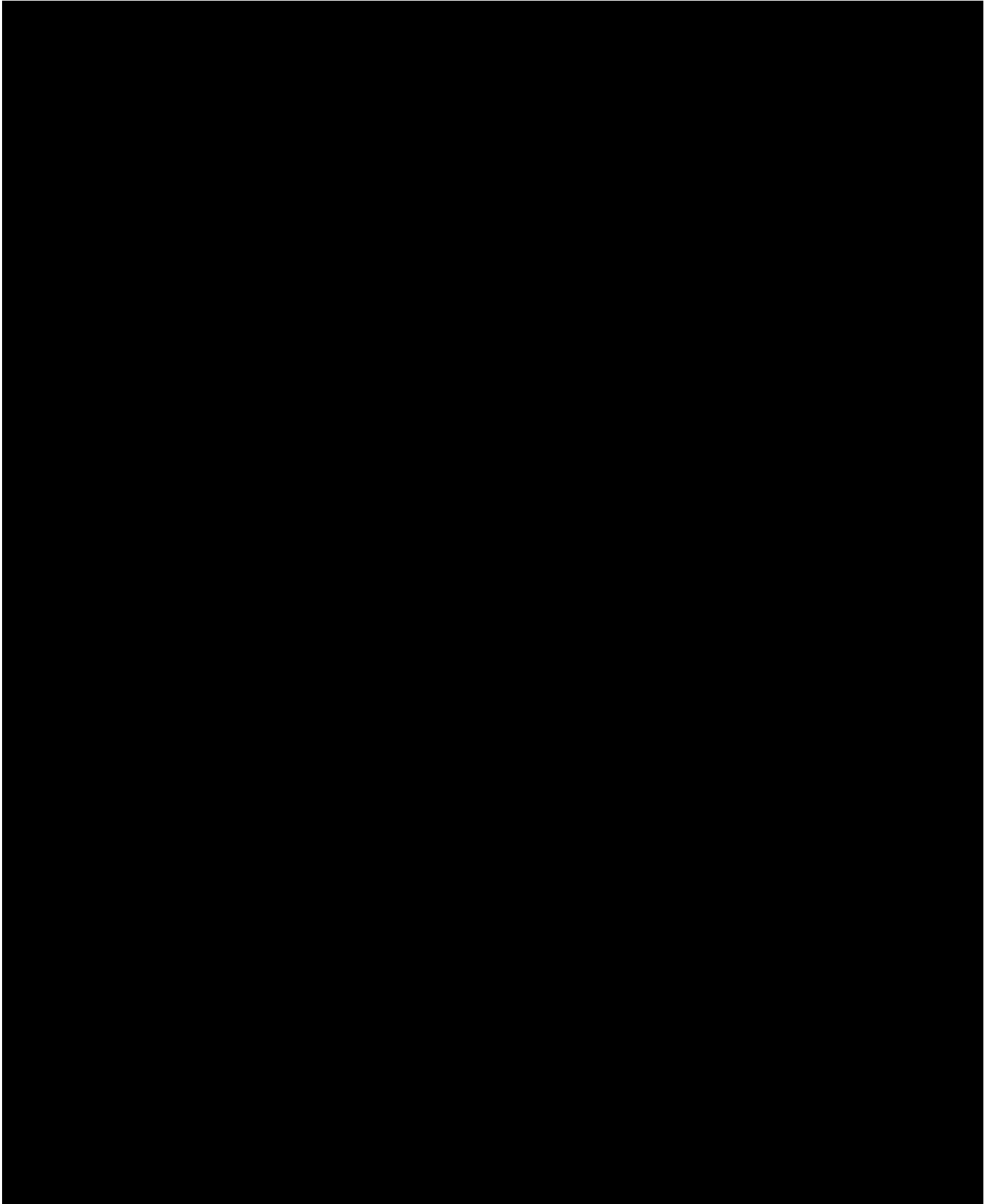


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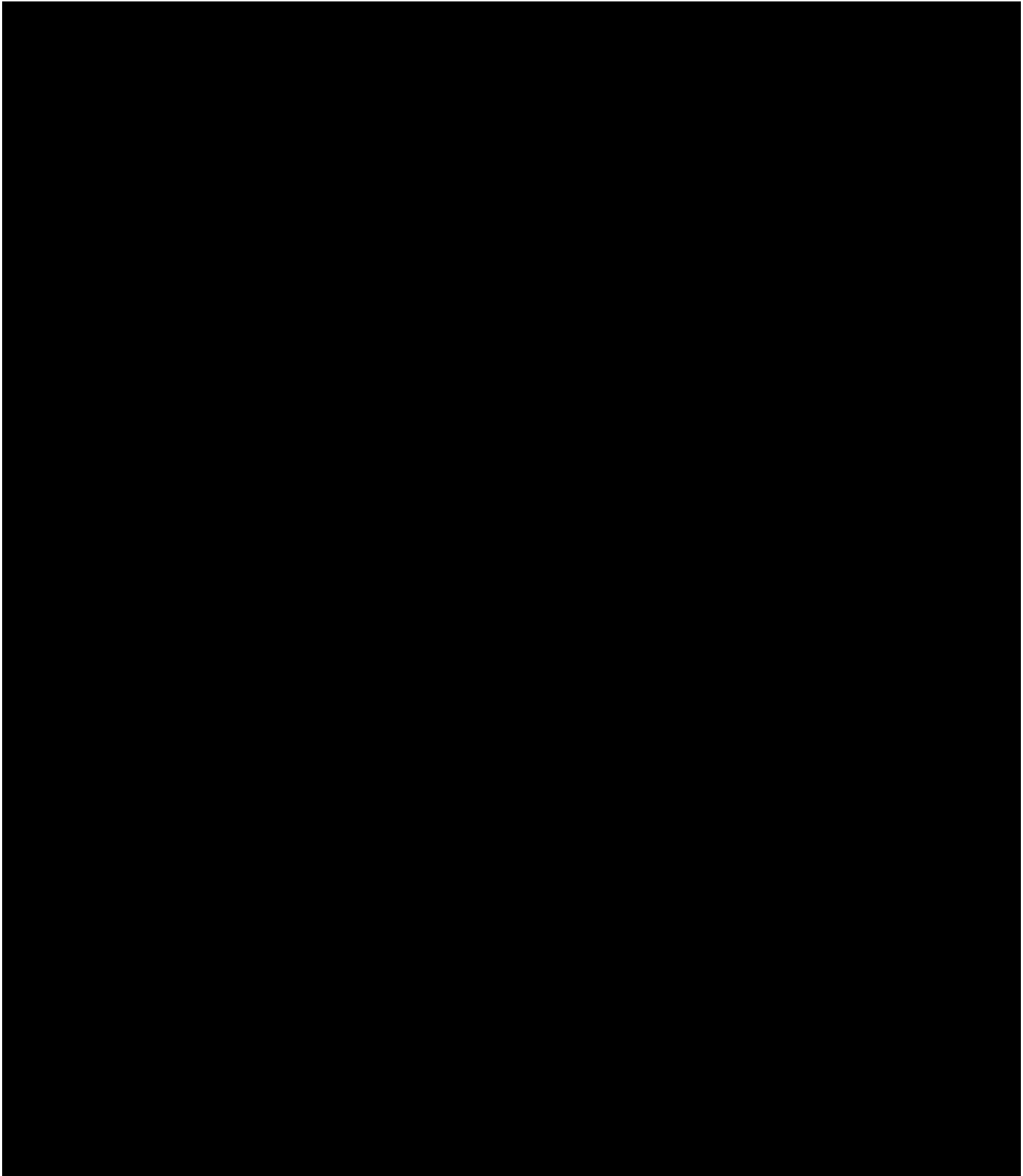




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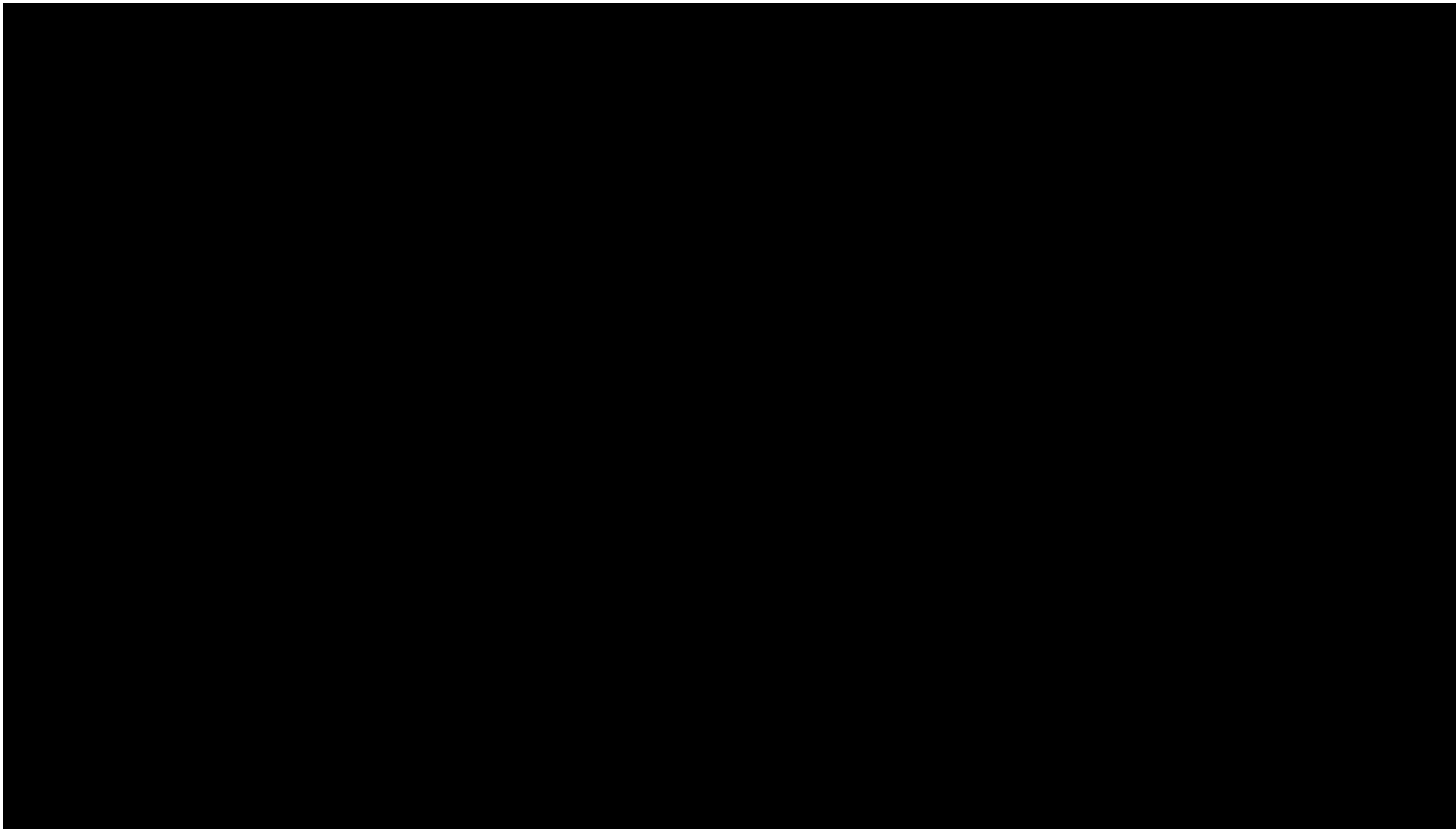
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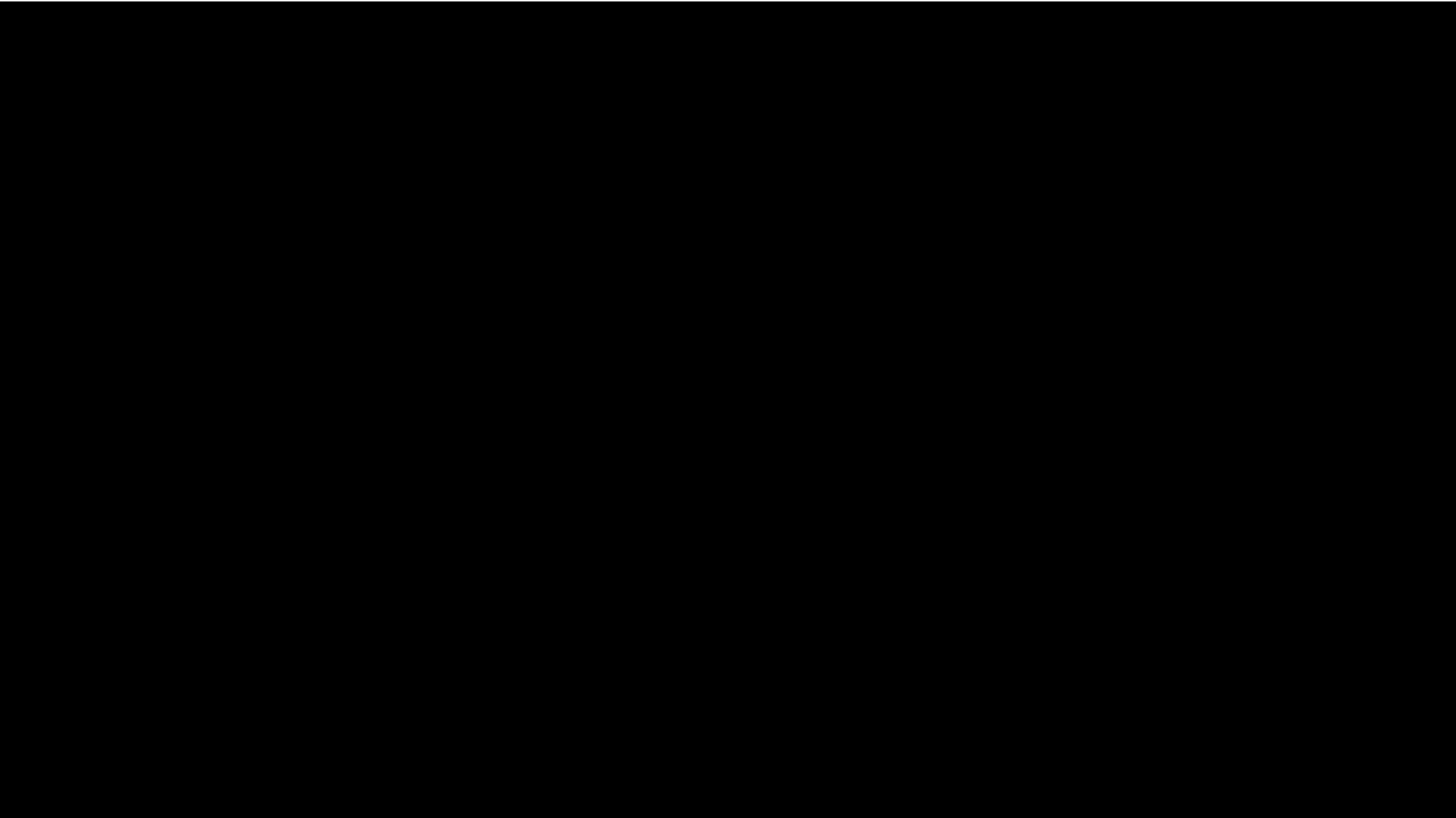
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# **EXHIBIT A**

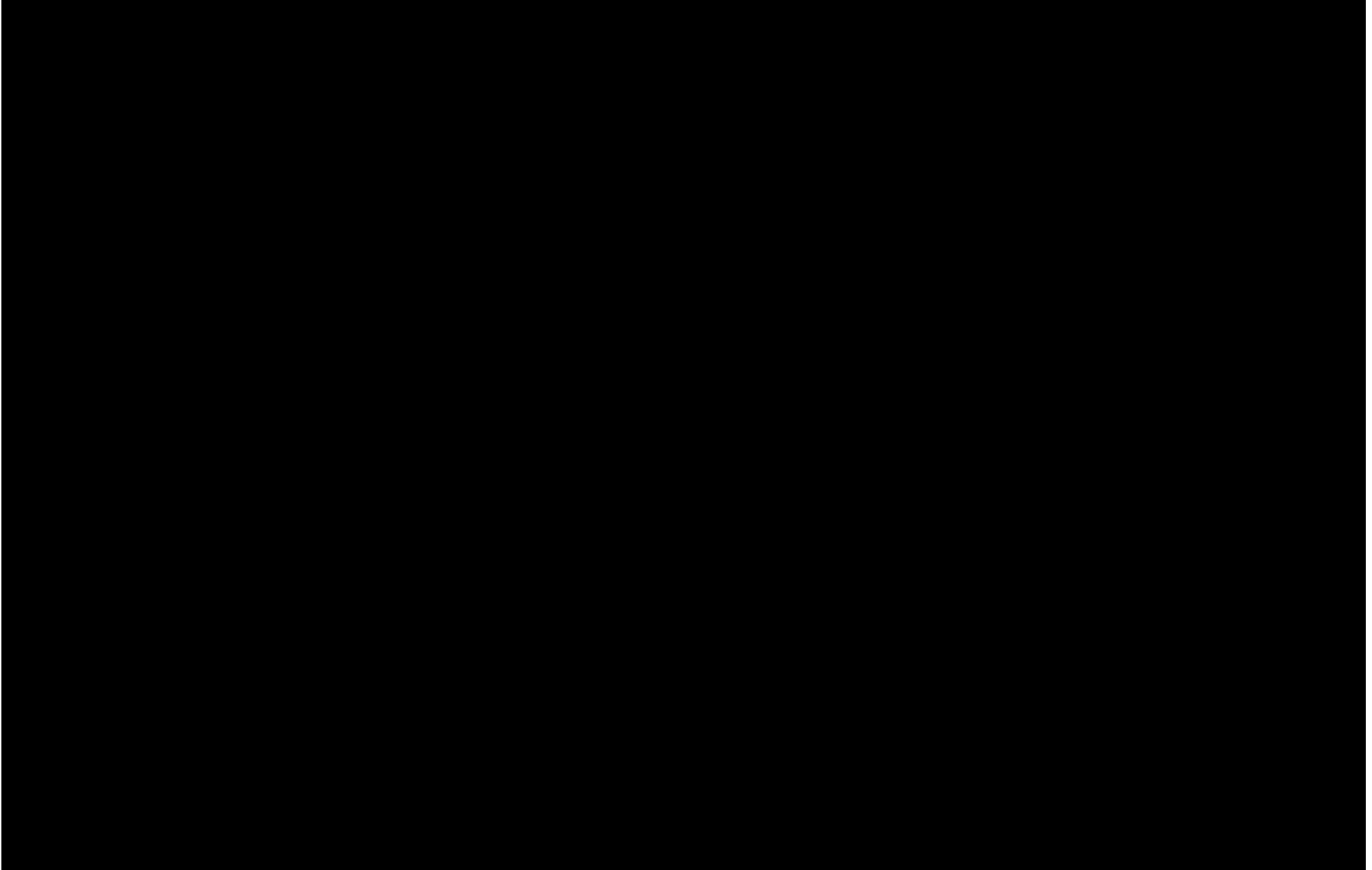
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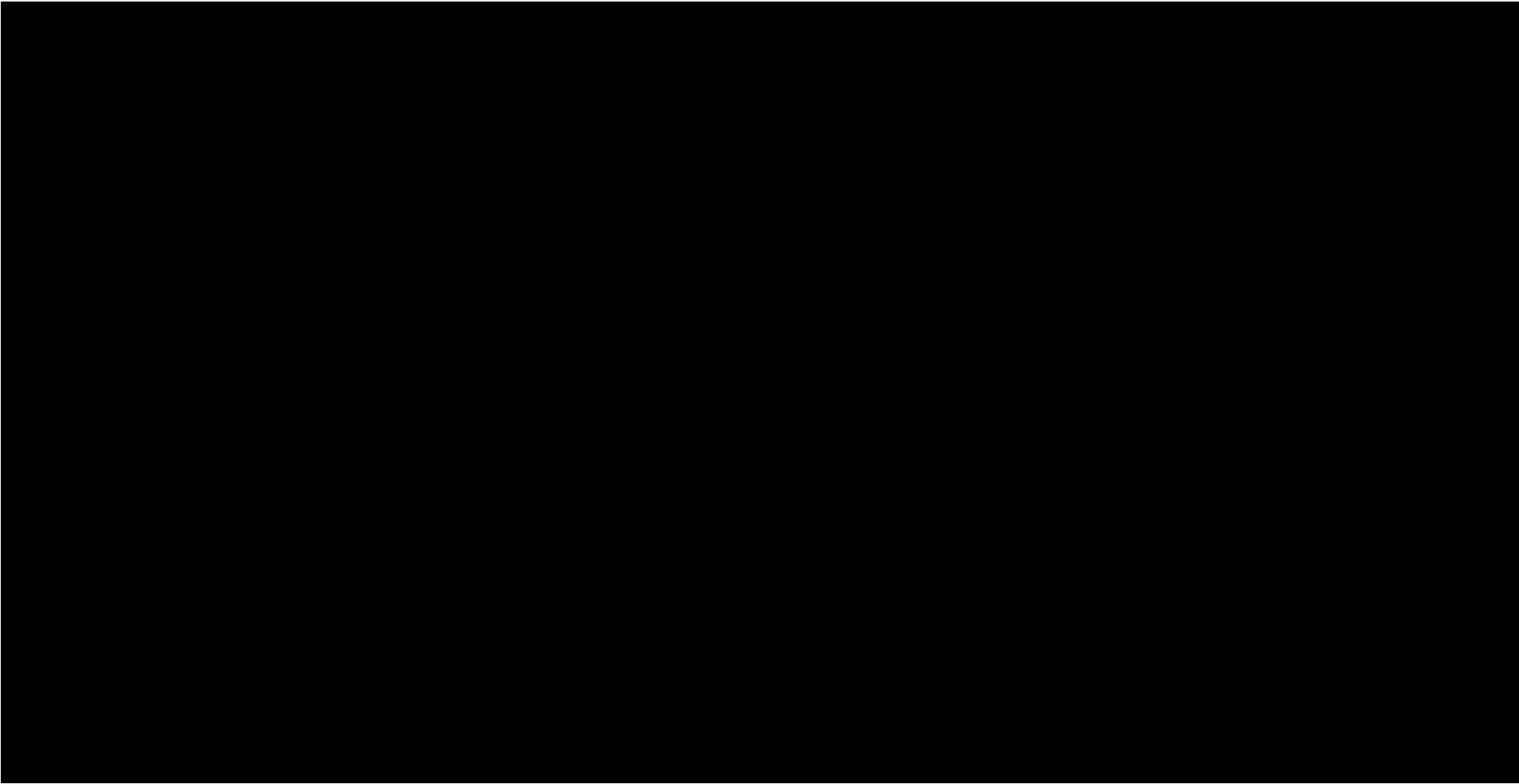
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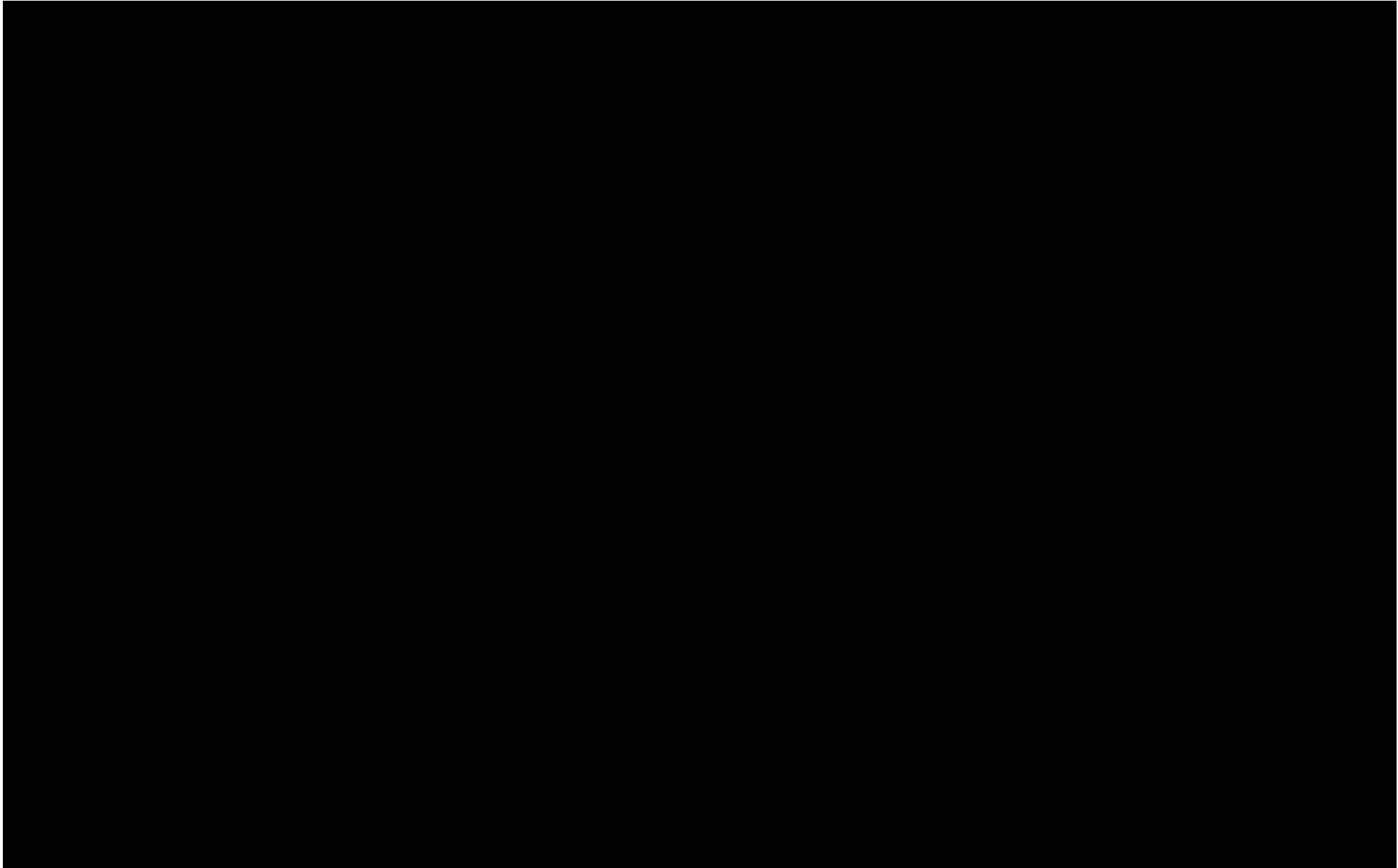


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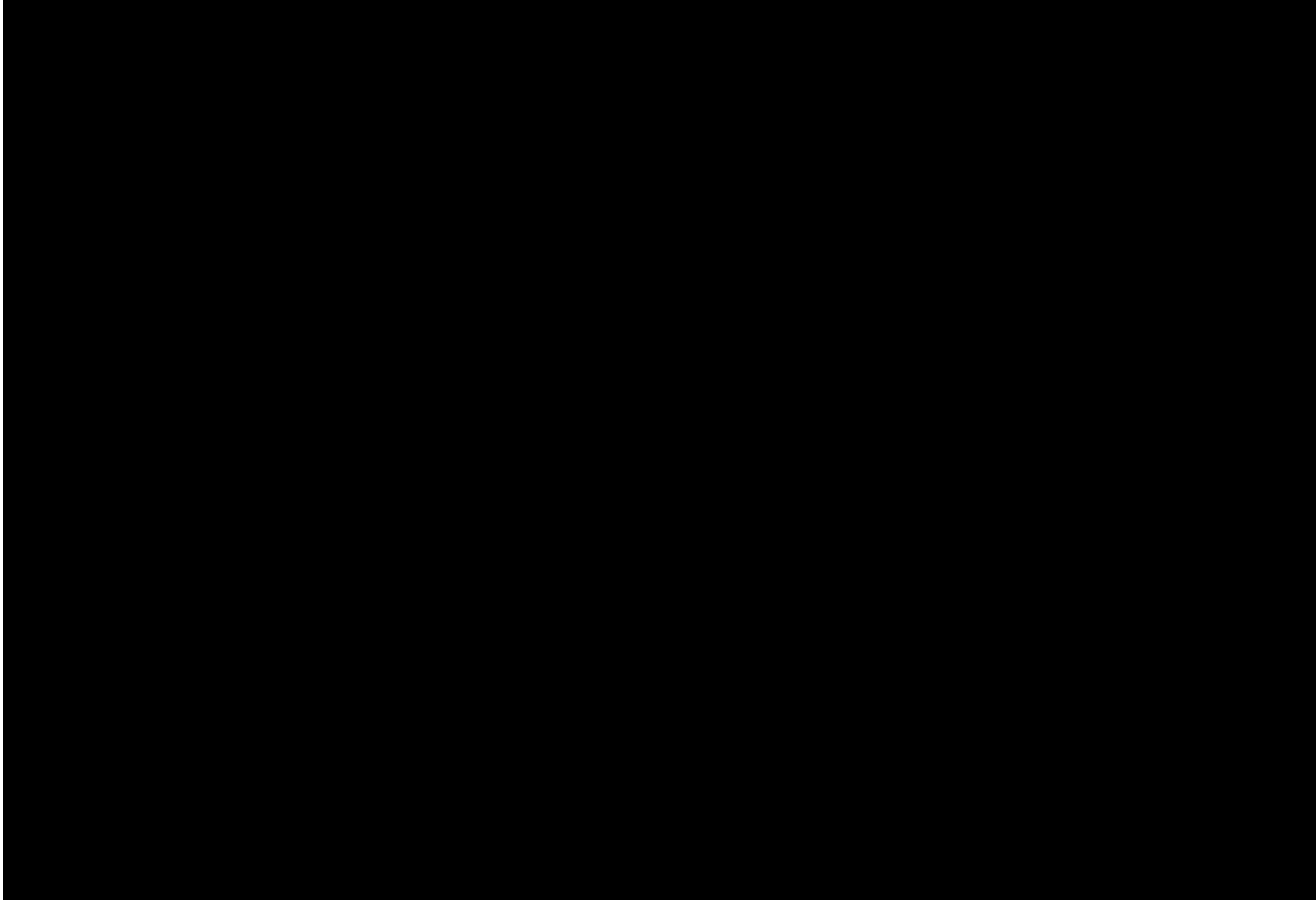
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,119,648 (“the ’648 Patent”) for Linagliptin, 0.5 mg dosage**  
**in Abbreviated New Drug Application (“ANDA”) No. 208335 (“the HEC ANDA”)**





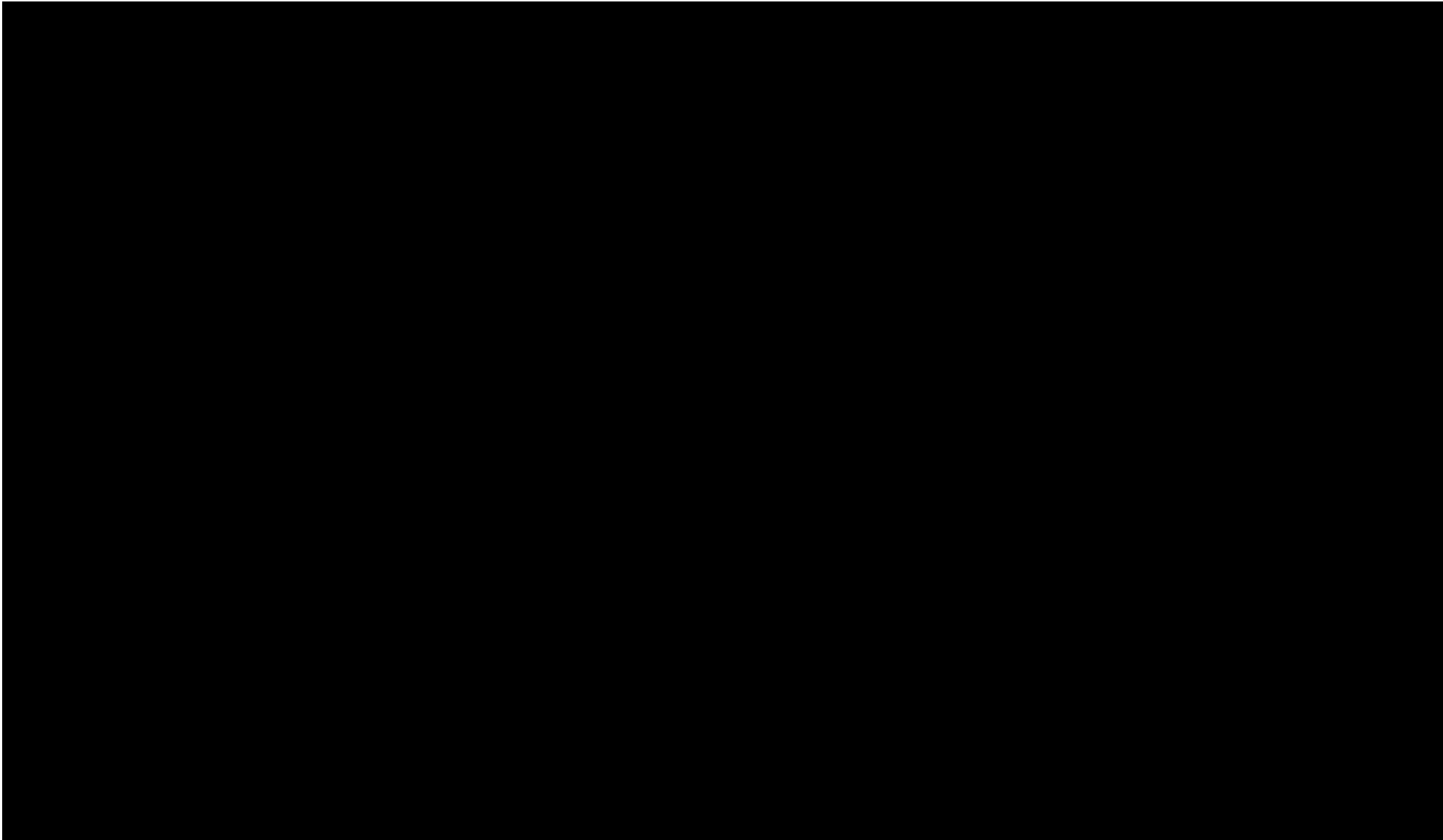
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**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**



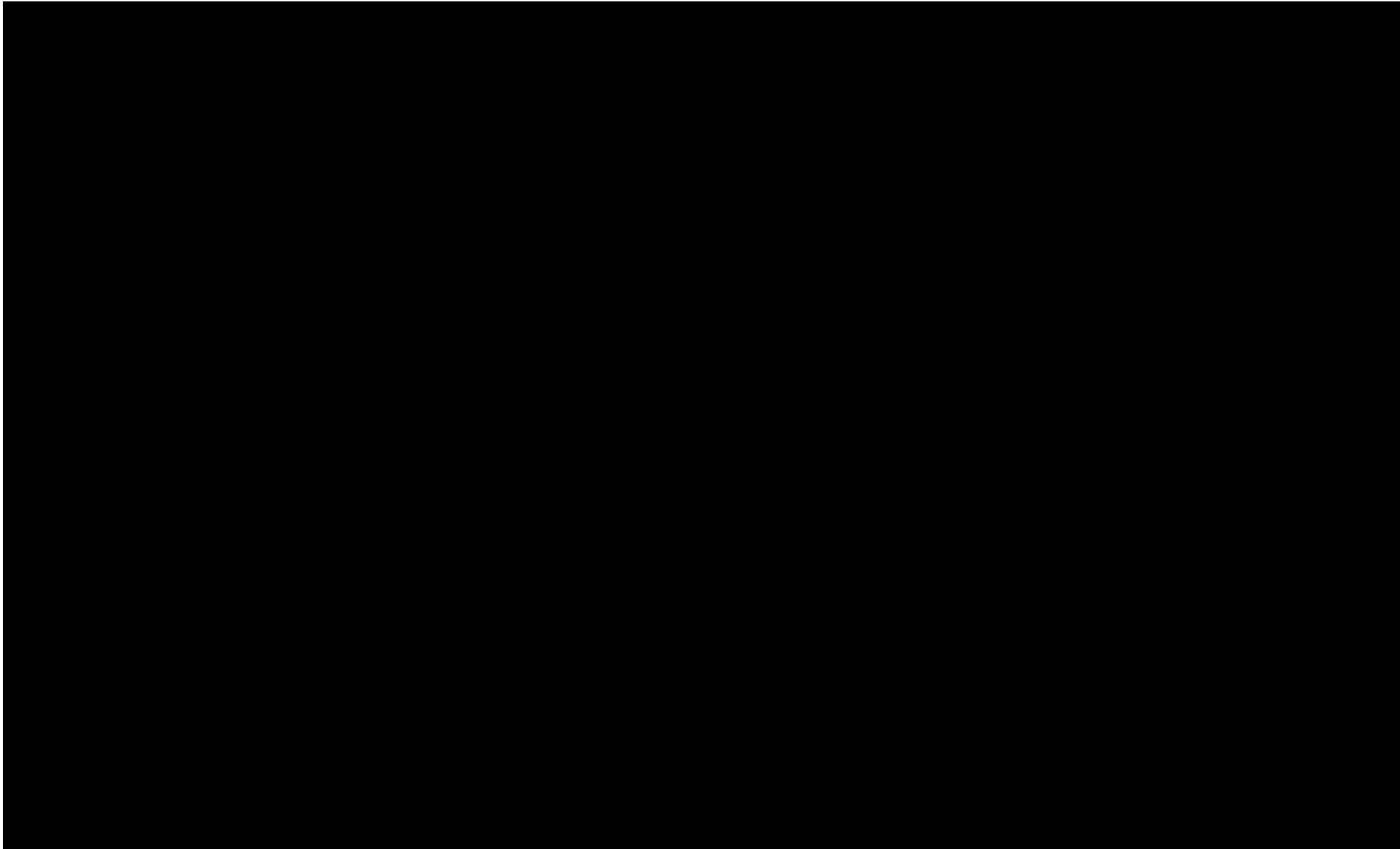
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,119,648 (“the ’648 Patent”)**

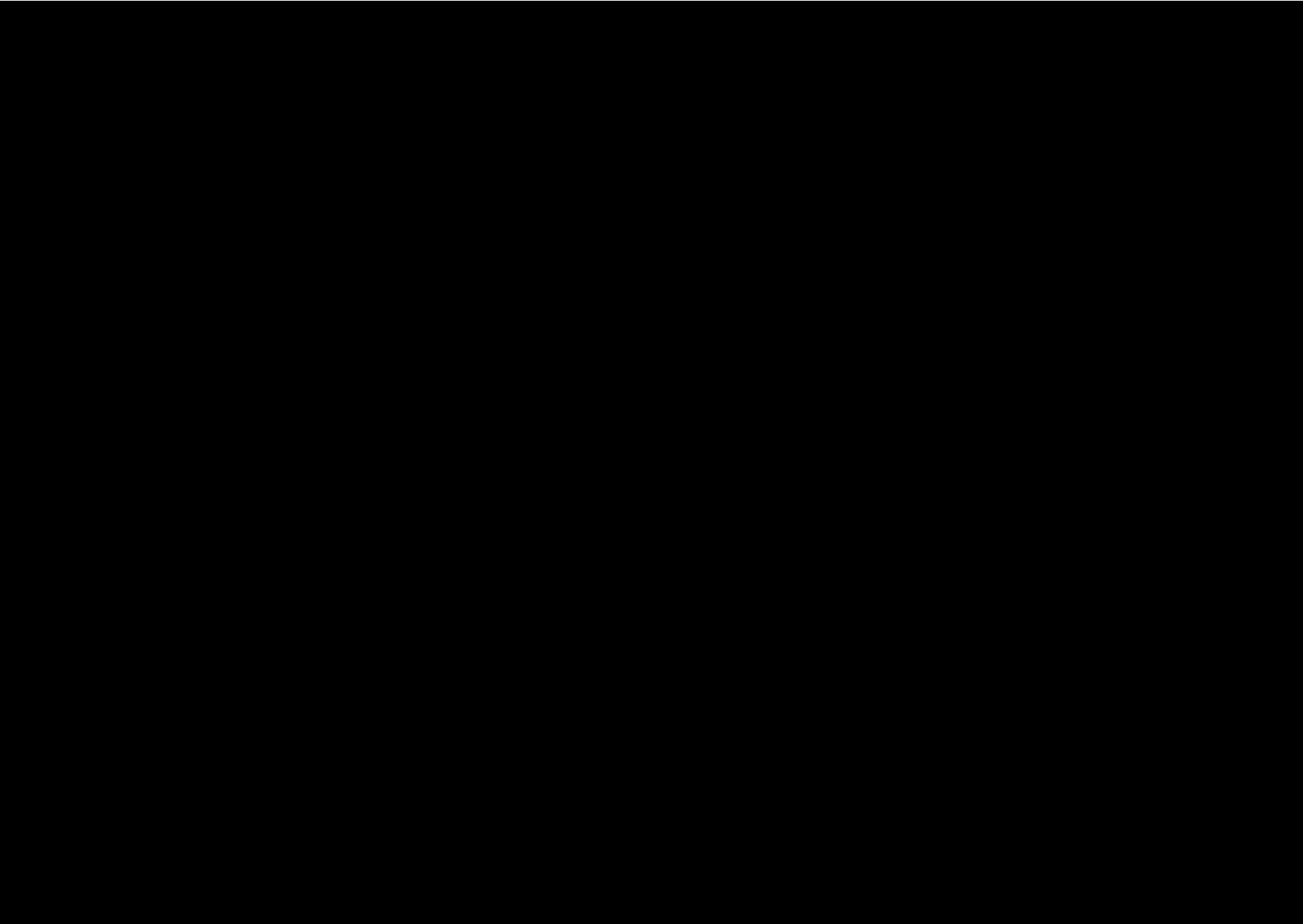


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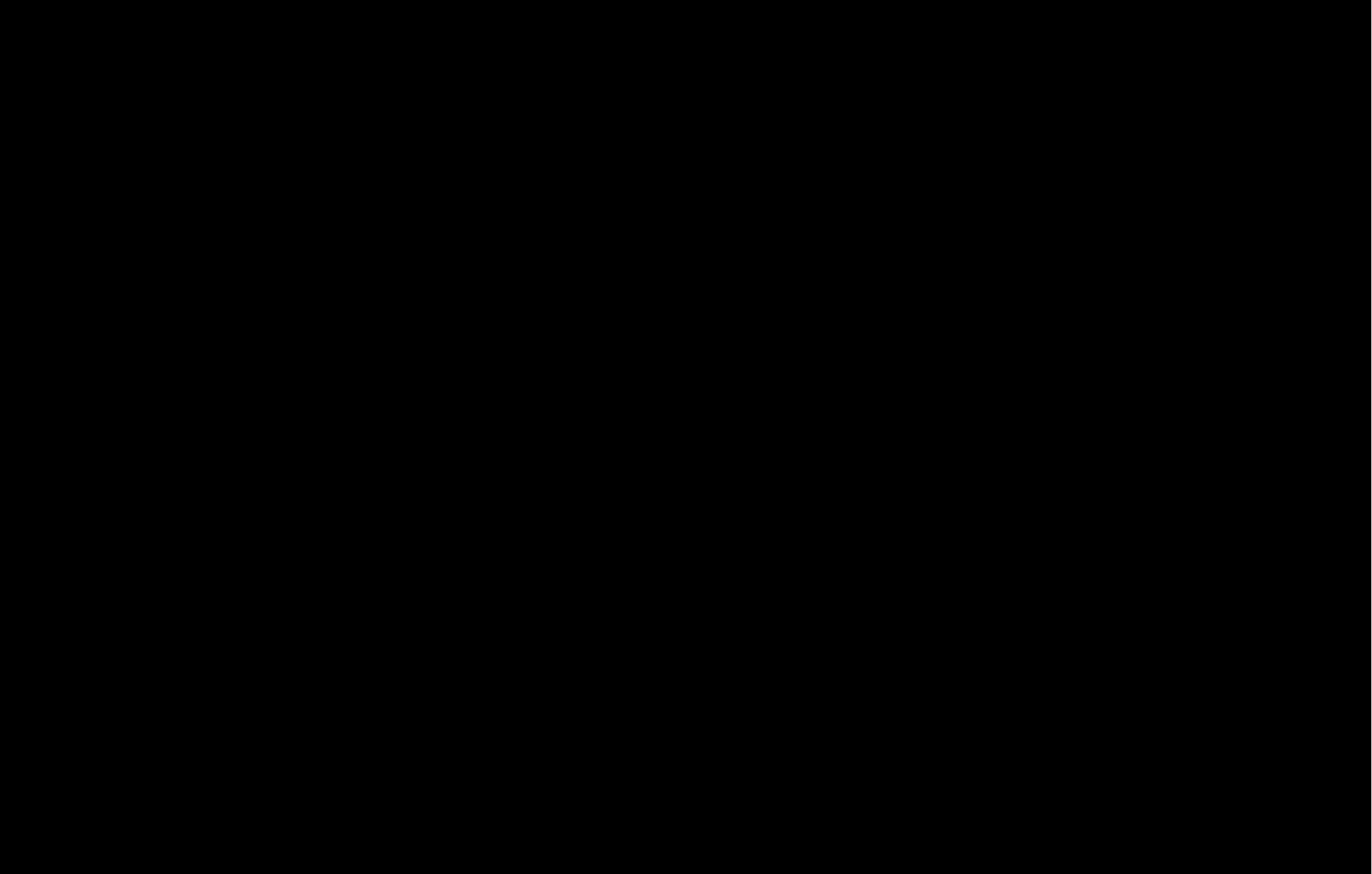
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,119,648 (“the ’648 Patent”) for**  
**Linagliptin and Metformin, 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages**  
**in Abbreviated New Drug Application (“ANDA”) No. 208336 (“the HEC ANDA”),**



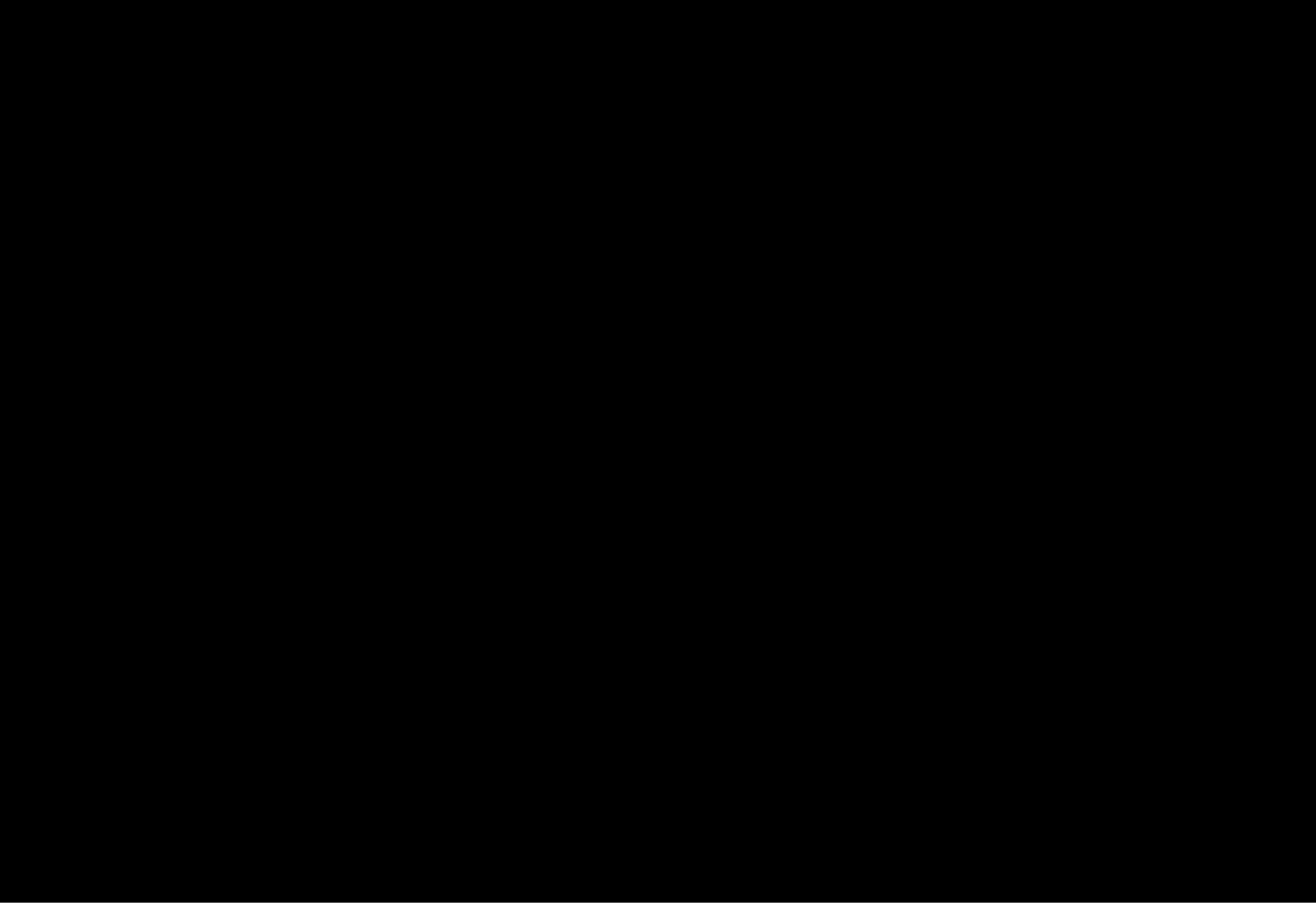
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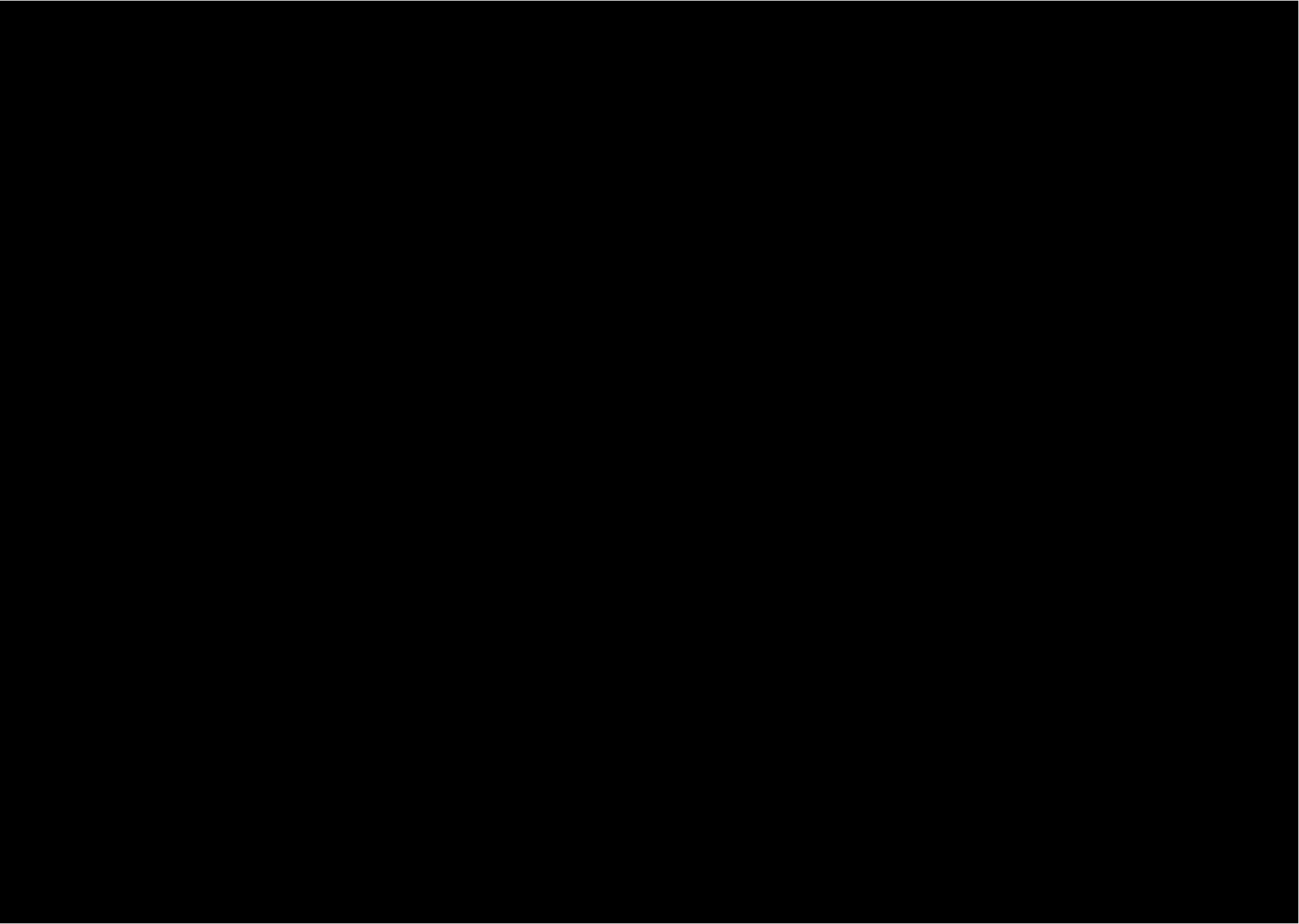
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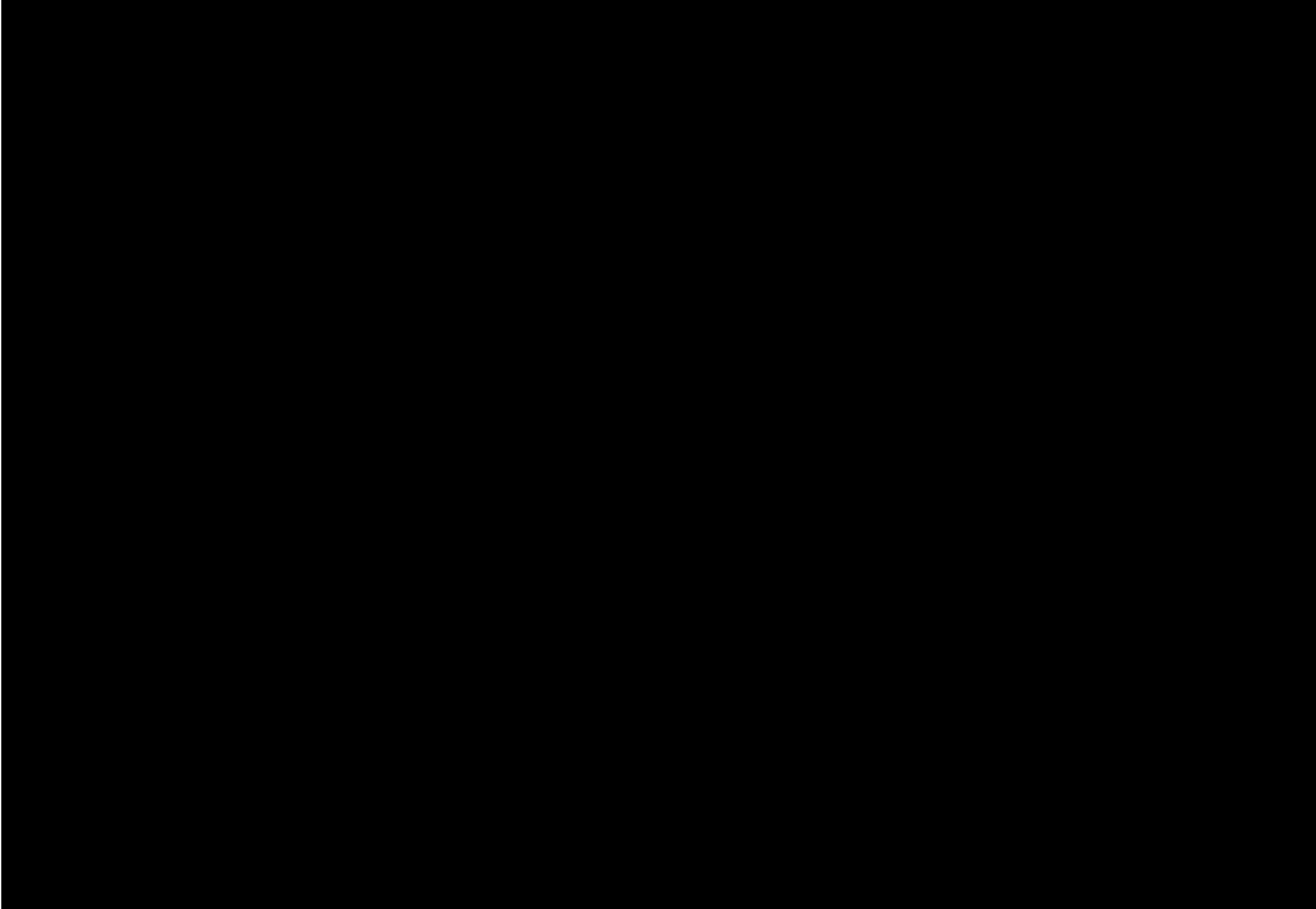
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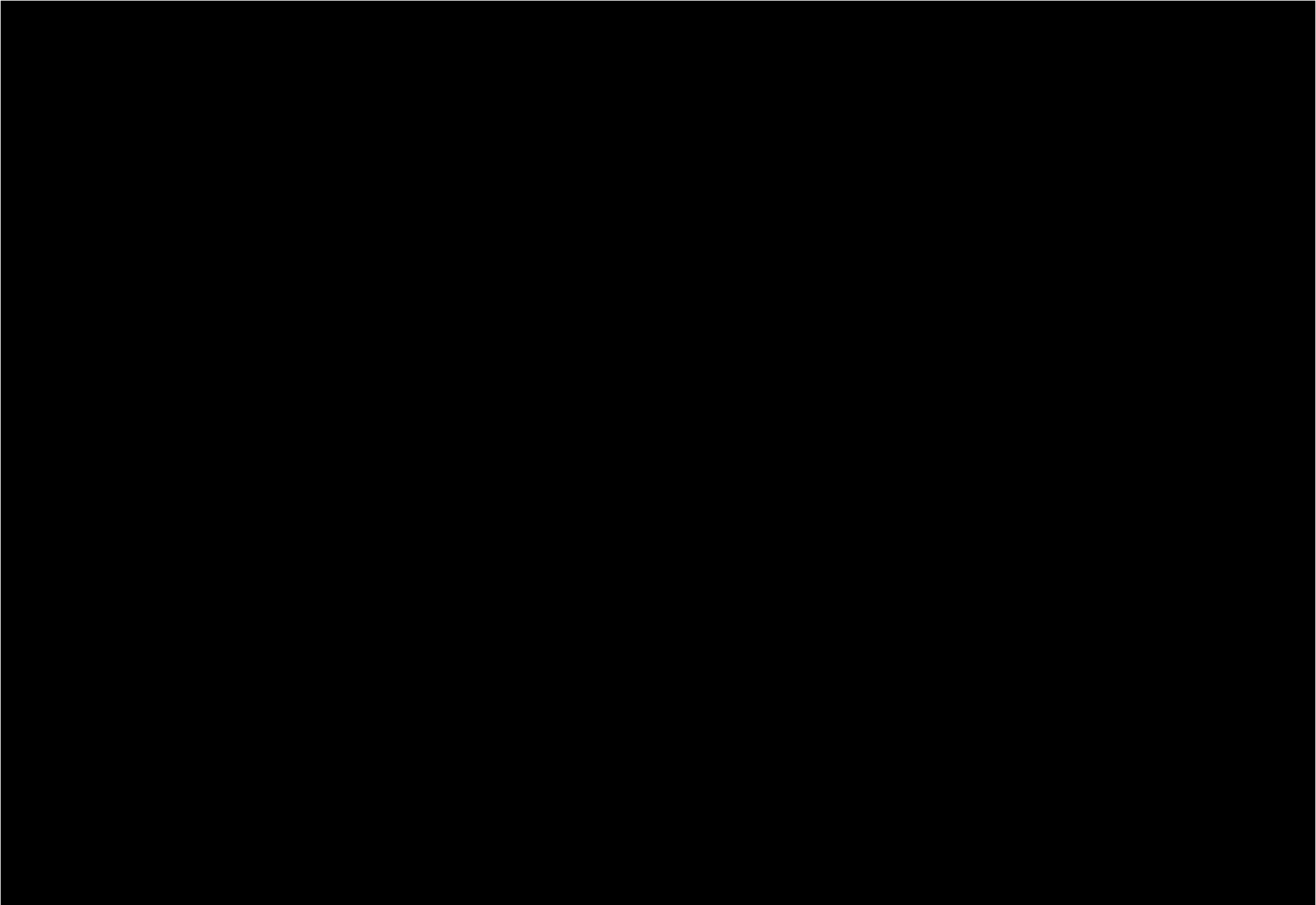


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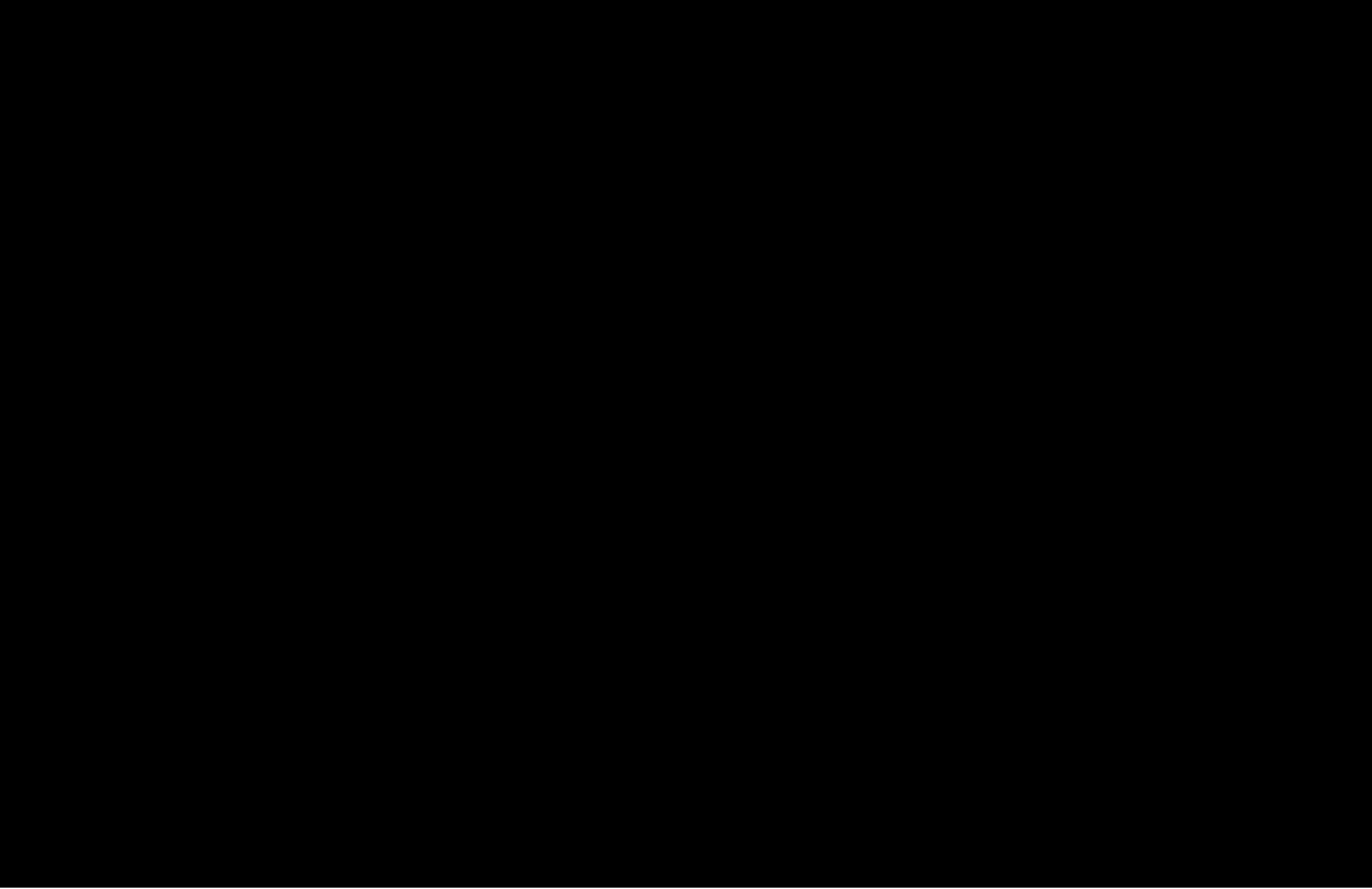




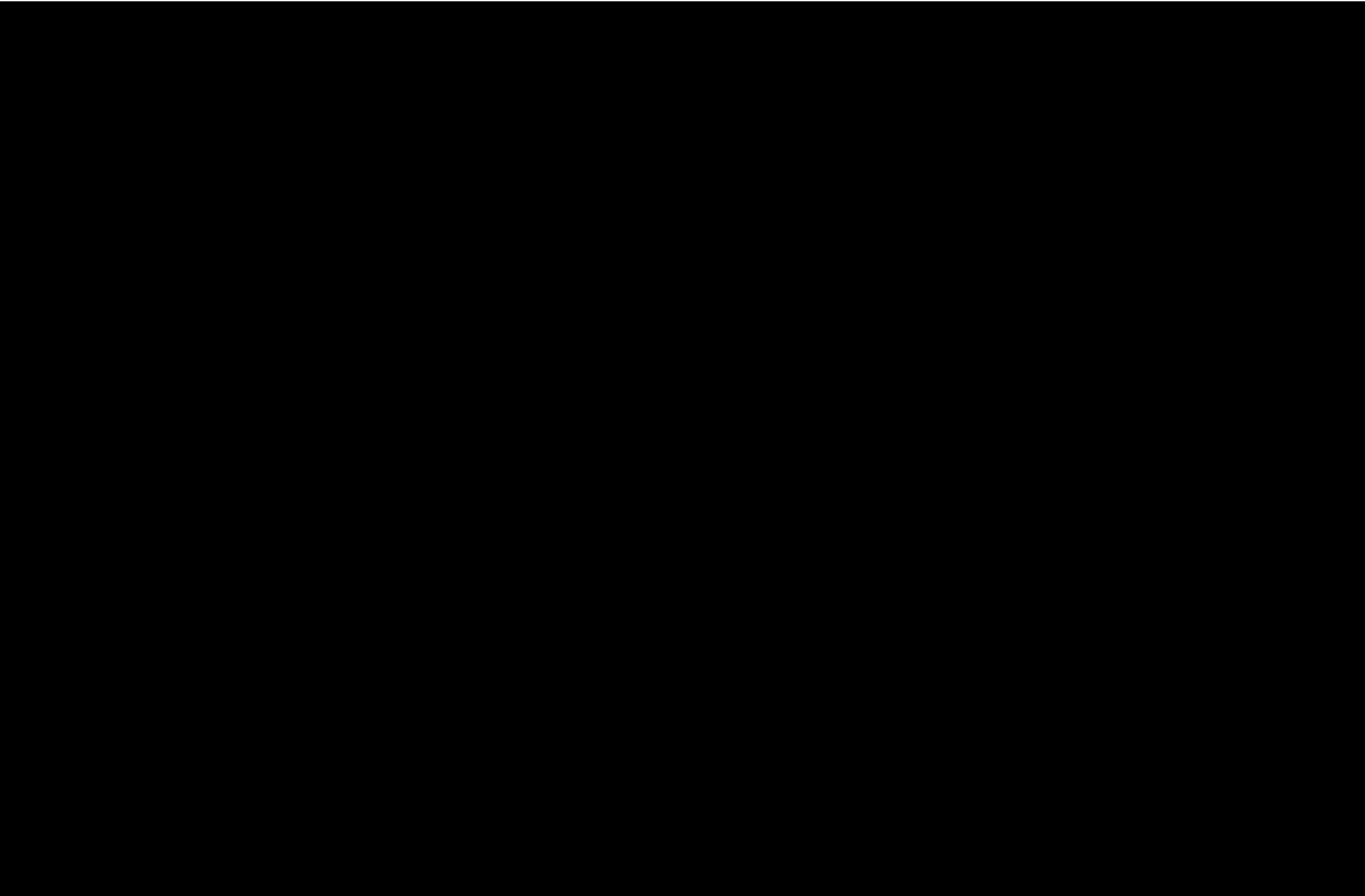
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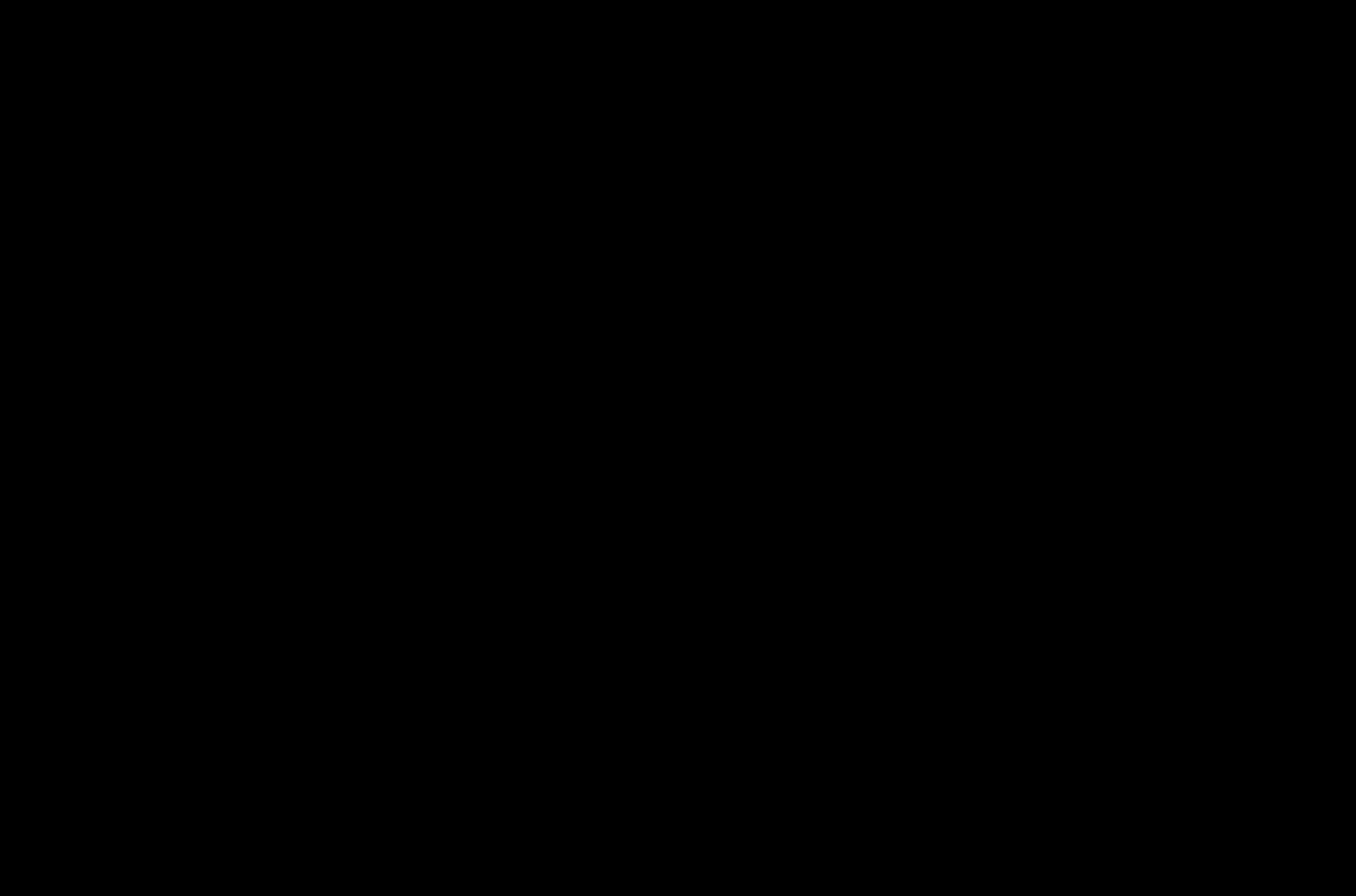


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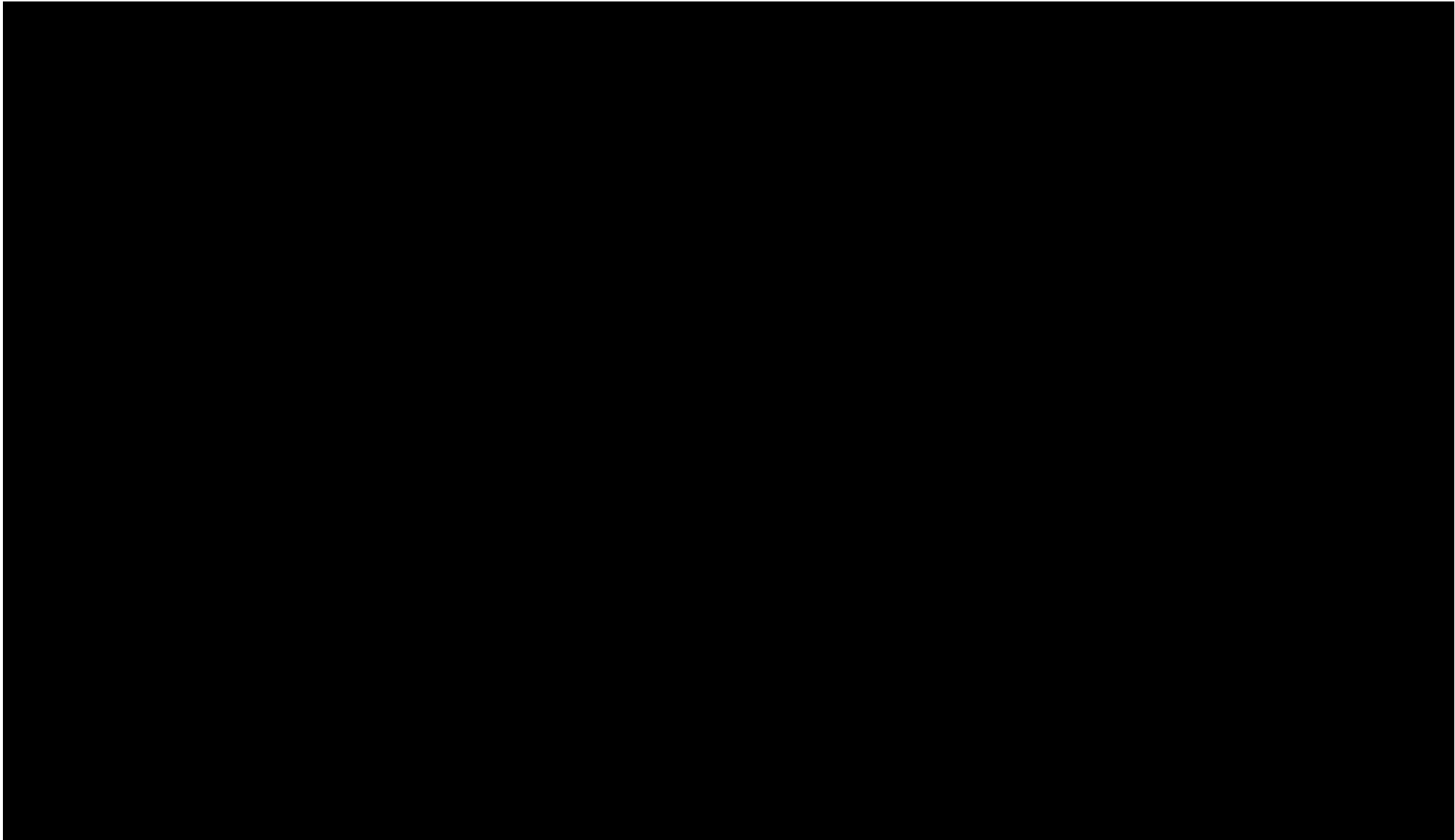
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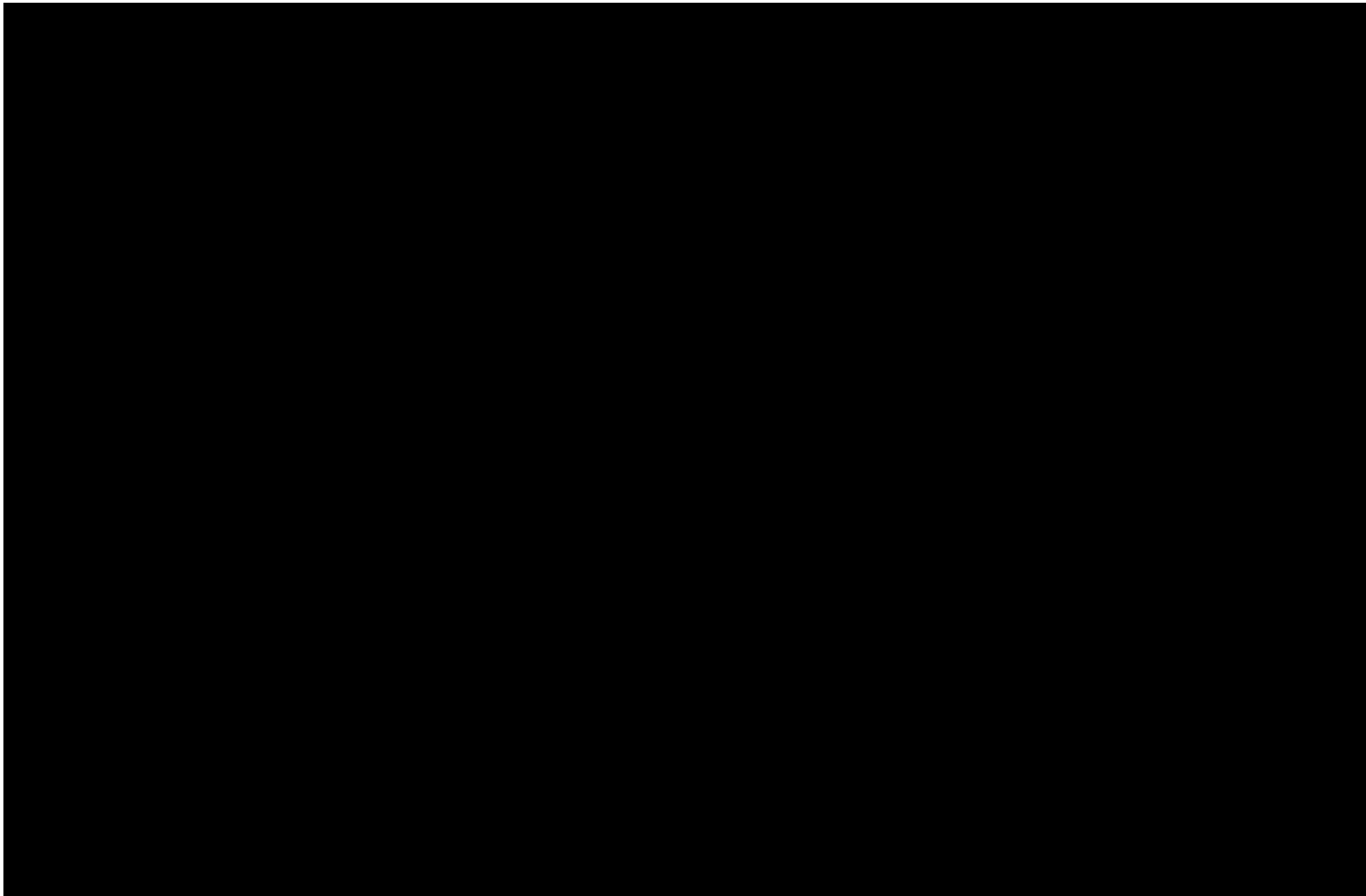
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,178,541 (“the ’541 Patent”) for**  
**Linagliptin and Metformin, 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages**  
**in Abbreviated New Drug Application (“ANDA”) No. 208336 (“the HEC ANDA”)**



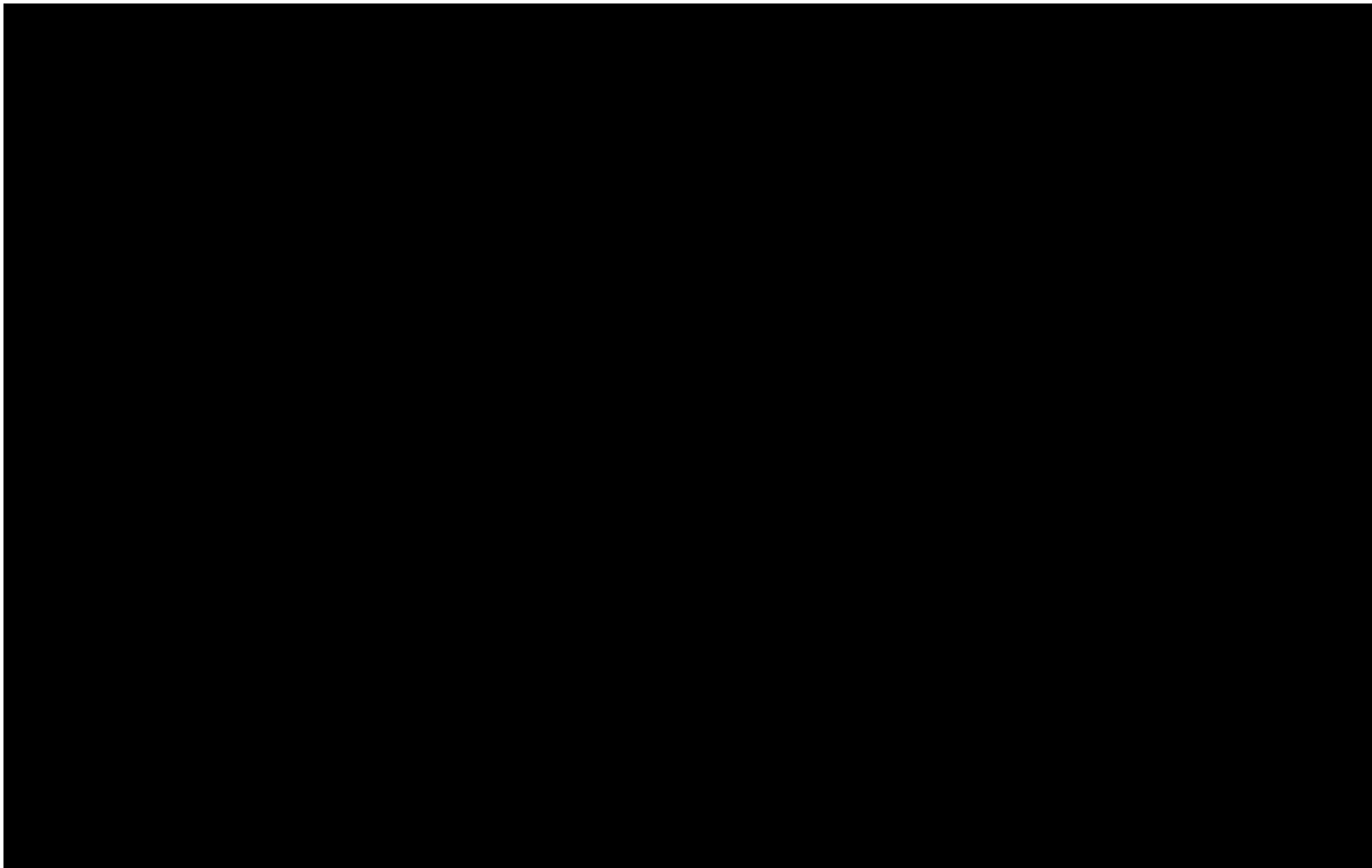
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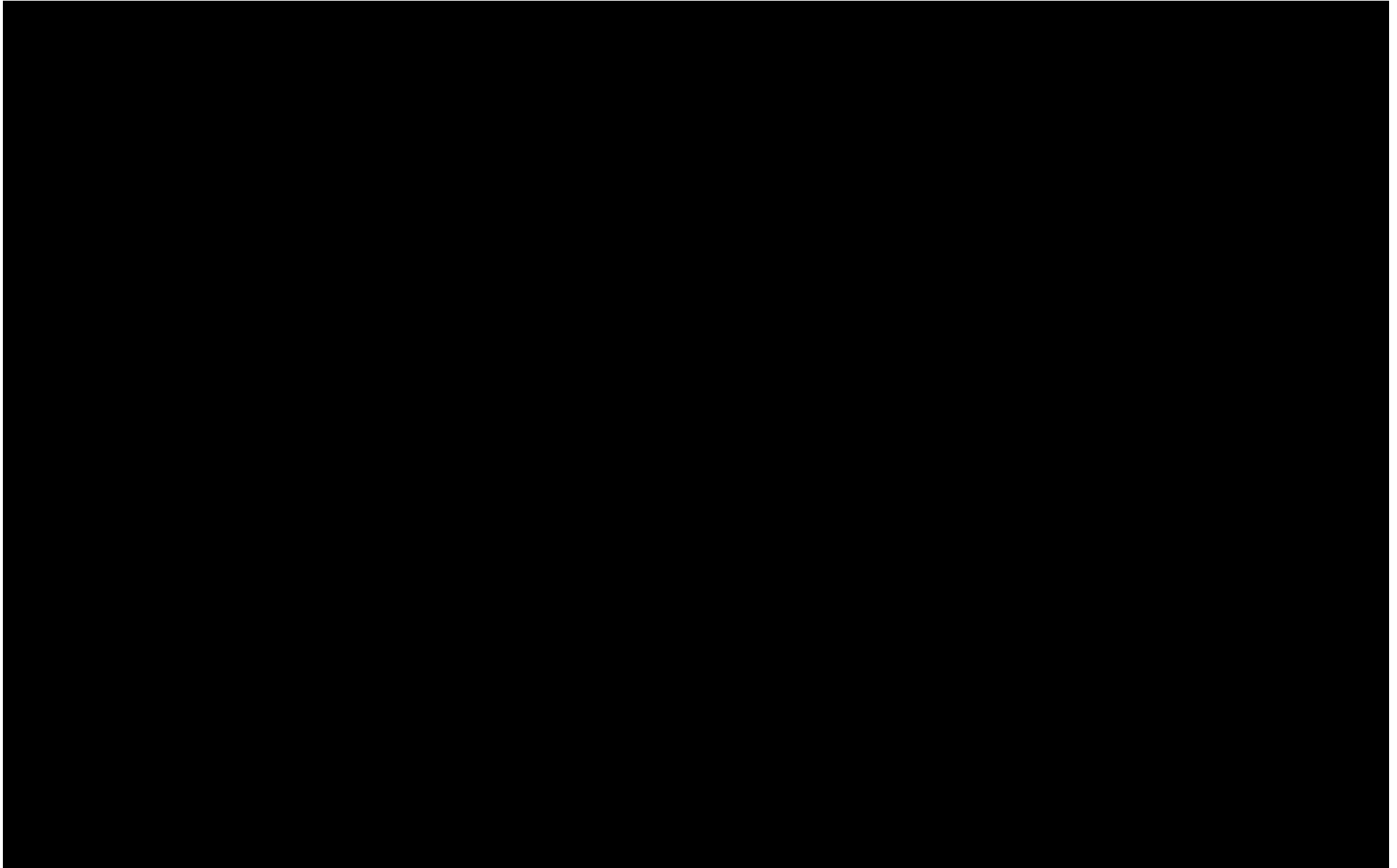
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**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**



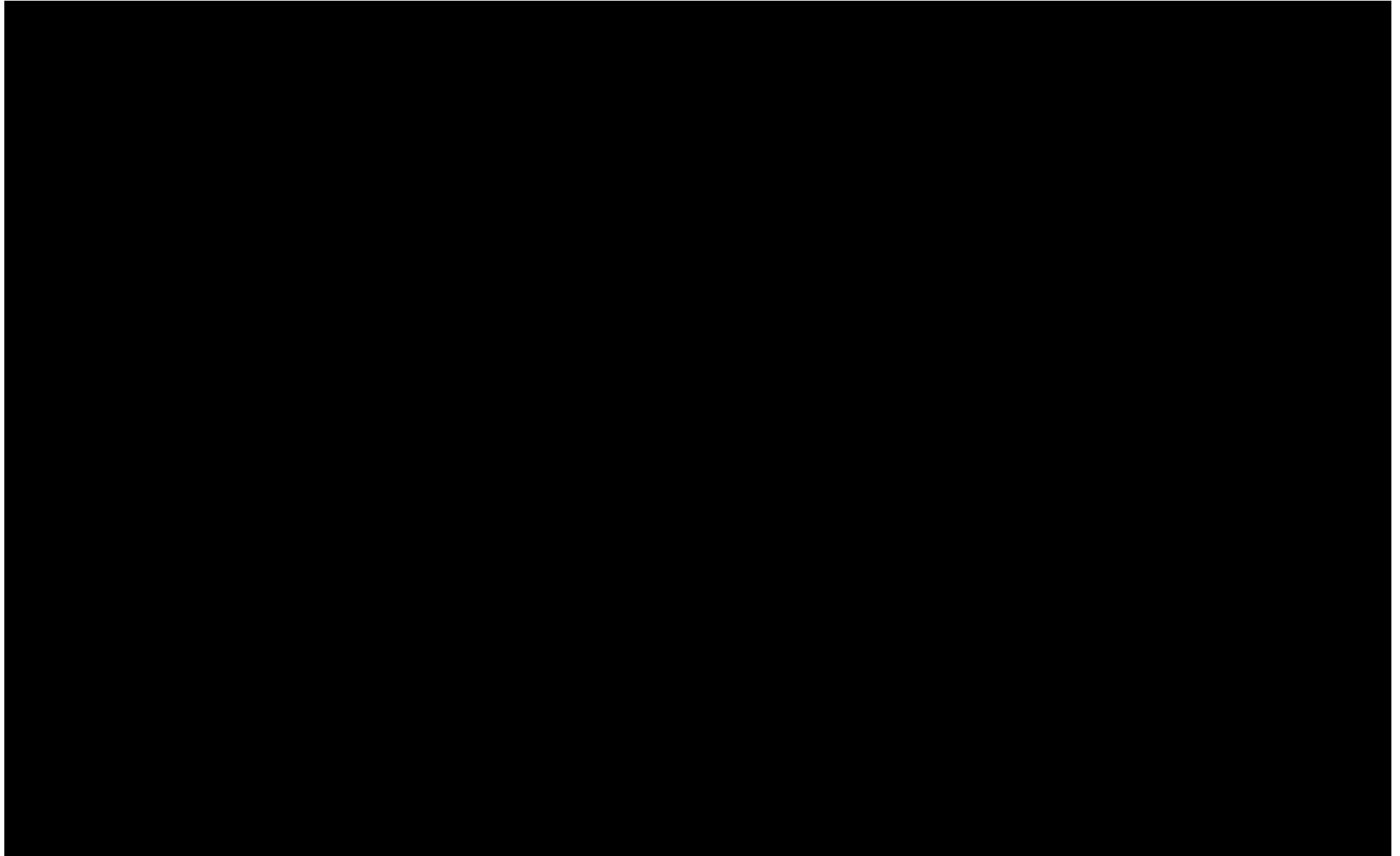
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,178,541 (“the ’541 Patent”)**



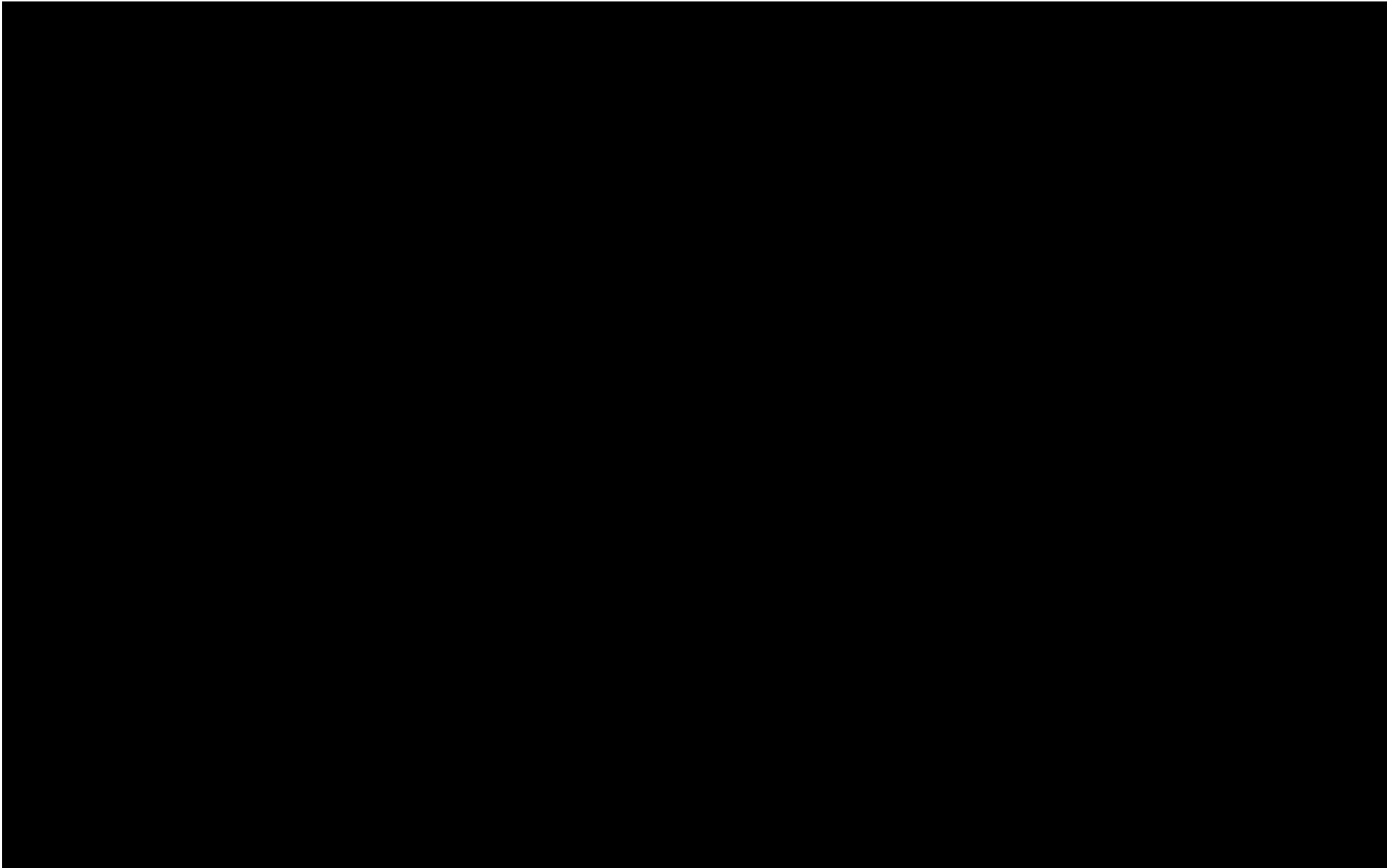
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,178,541 (“the ’541 Patent”)**



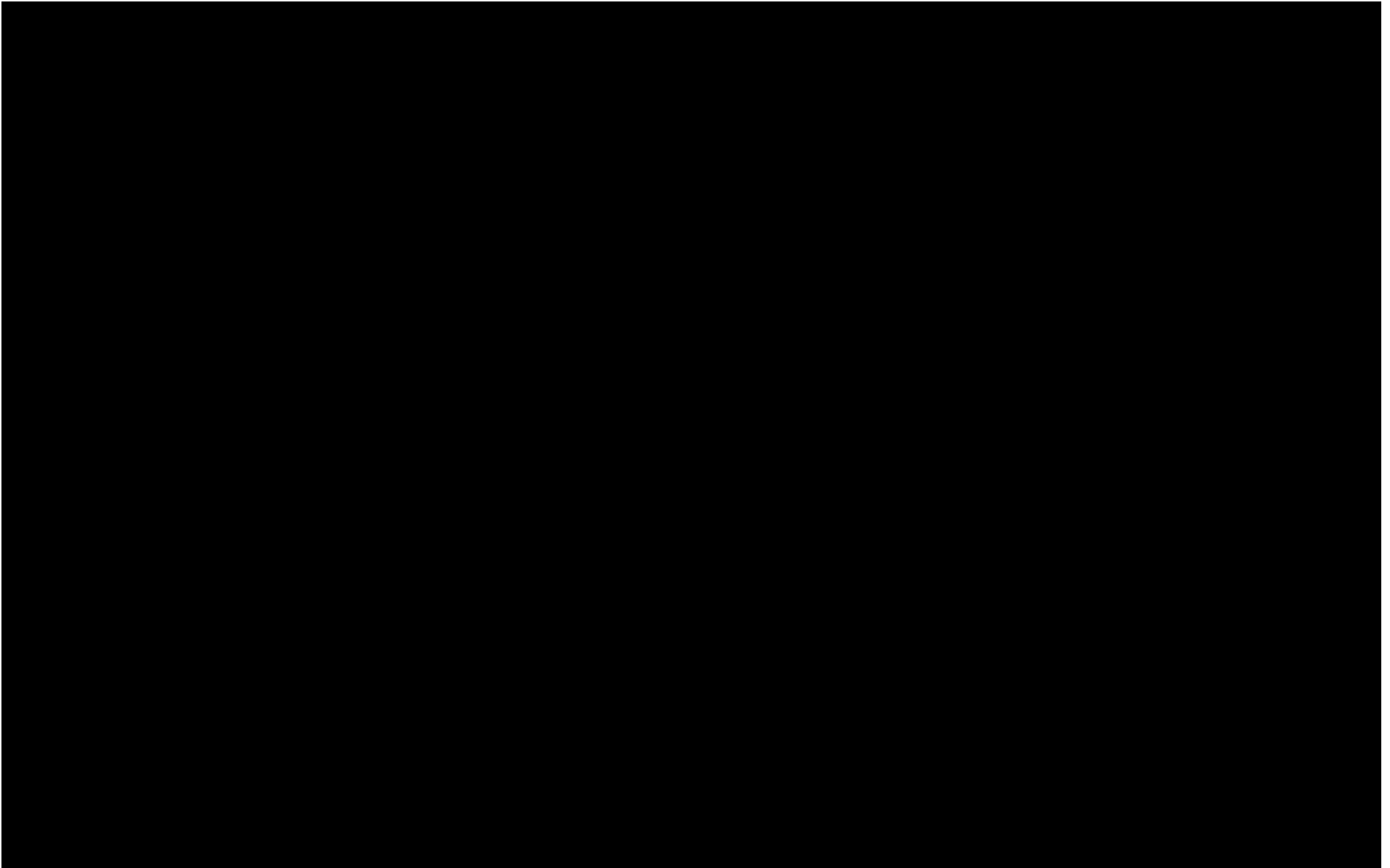
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,178,541 (“the ’541 Patent”)**



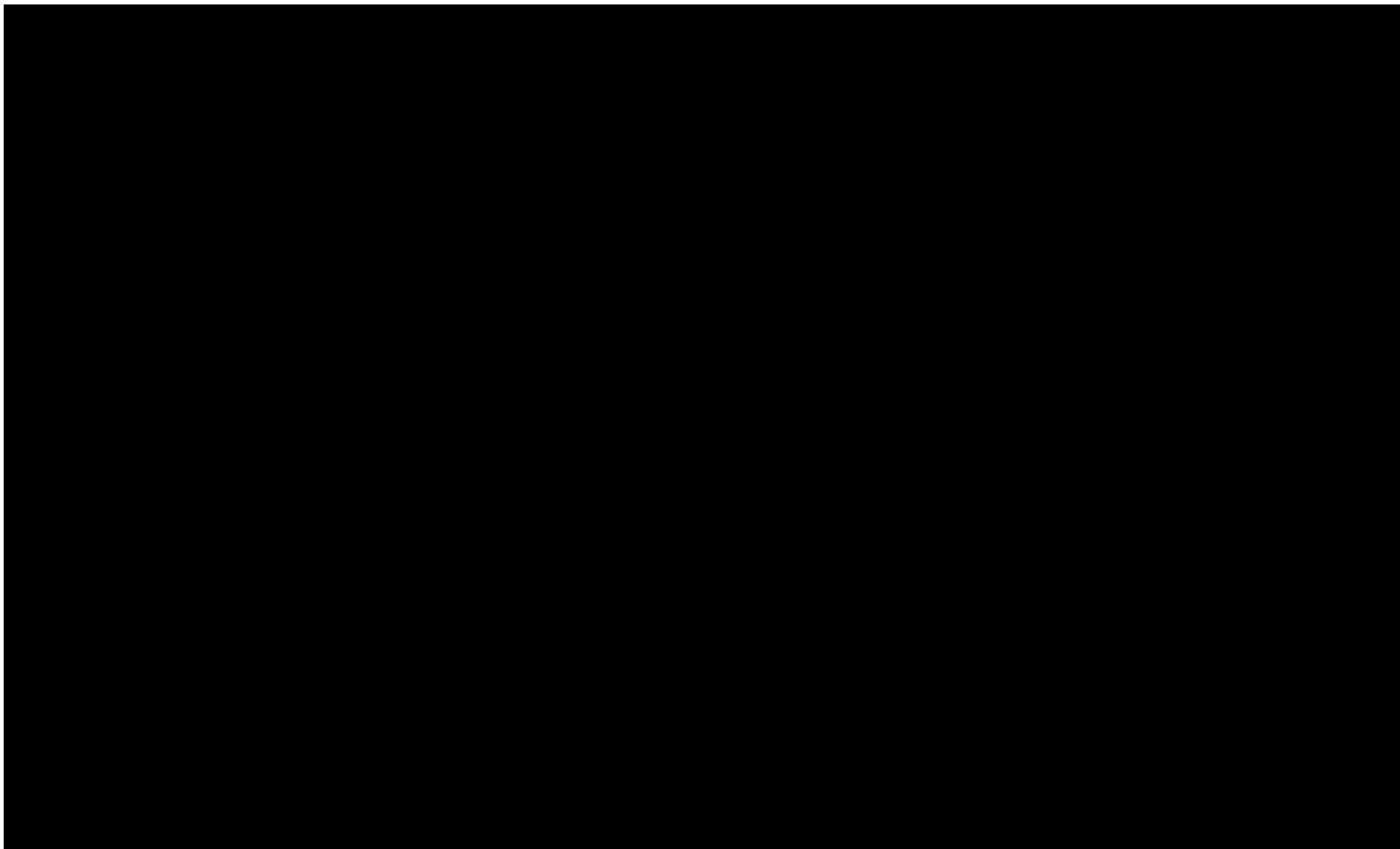
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,178,541 (“the ’541 Patent”)**



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

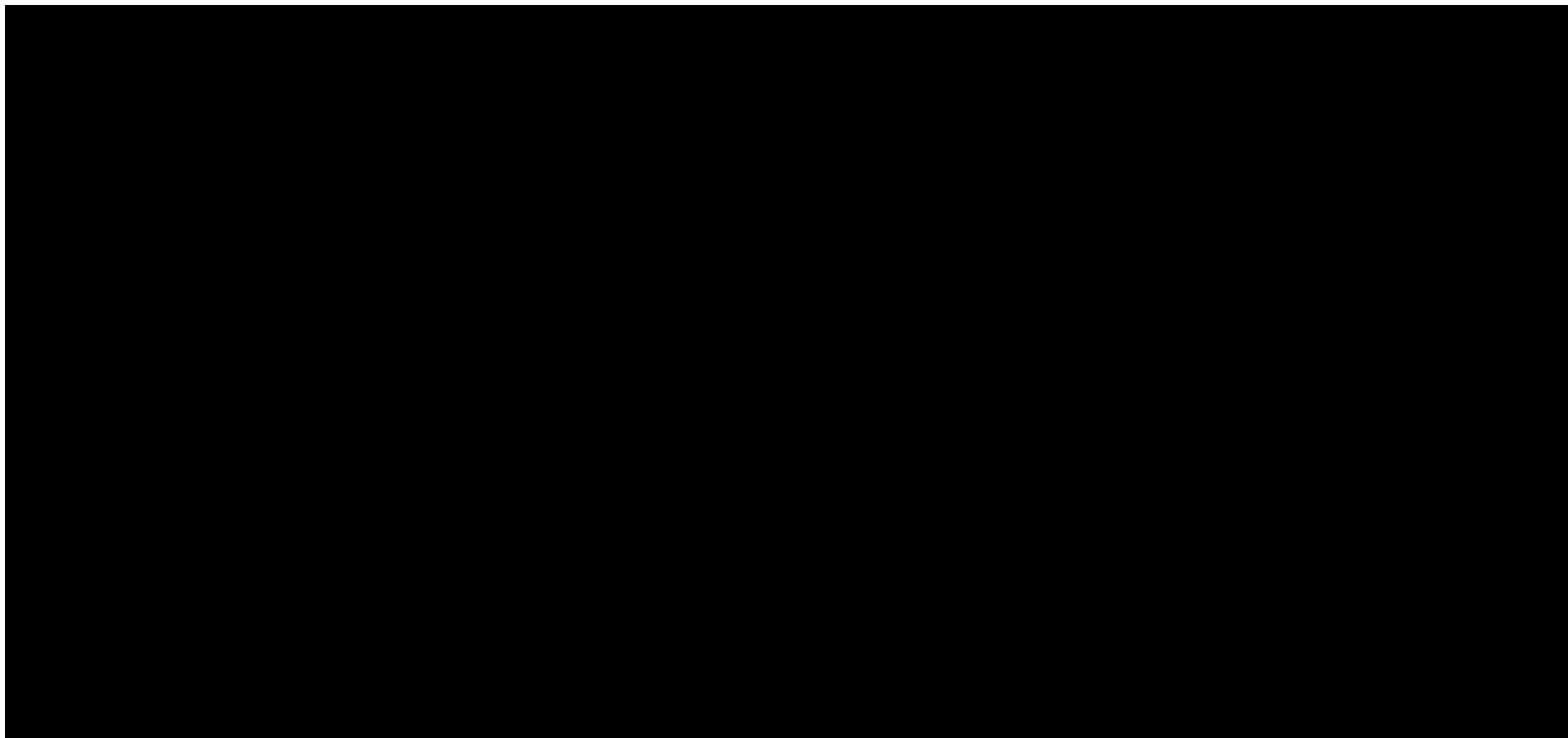
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,178,541 (“the ’541 Patent”)**



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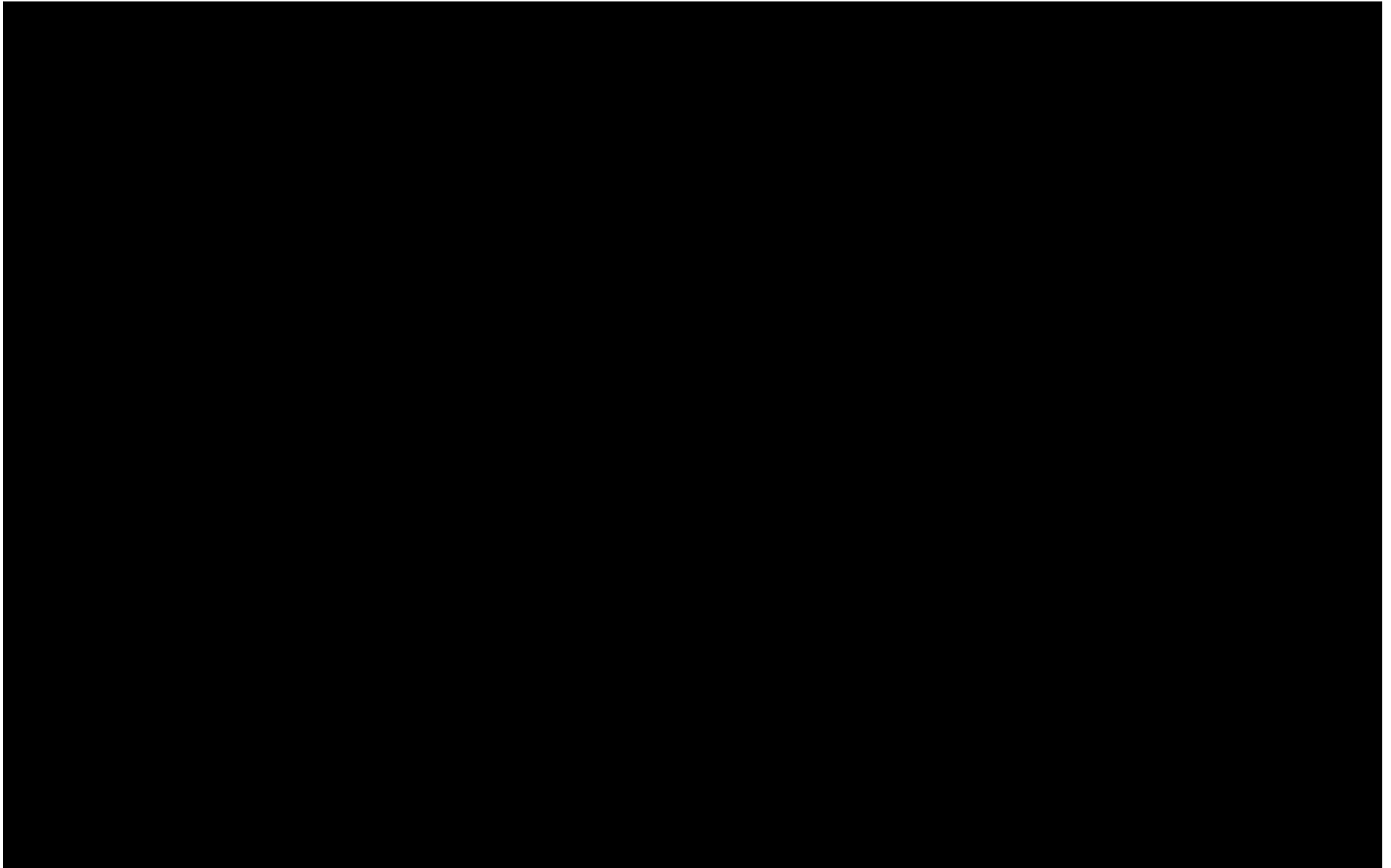
**DEFENDANTS’ NON-INFRINGEMENT CONTENTION CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”) for Linagliptin, 0.5 mg dosage**  
**in Abbreviated New Drug Application (“ANDA”) No. 208335 (“the HEC ANDA”)**

Subject to the foregoing, Defendants provide in good faith the following non-infringement contentions for the asserted claims of the ’927 patent. Defendants reserve the right to amend their non-infringement contentions to take into account any information provided during discovery and the Court’s claim construction (if any) for terms recited in the claims of this patent. Because Plaintiffs have yet to produce the samples of TRADJENTA<sup>®</sup>, Defendants are unable to provide full and complete non-infringement contentions concerning the ’927 patent and reserve all rights to do so.



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

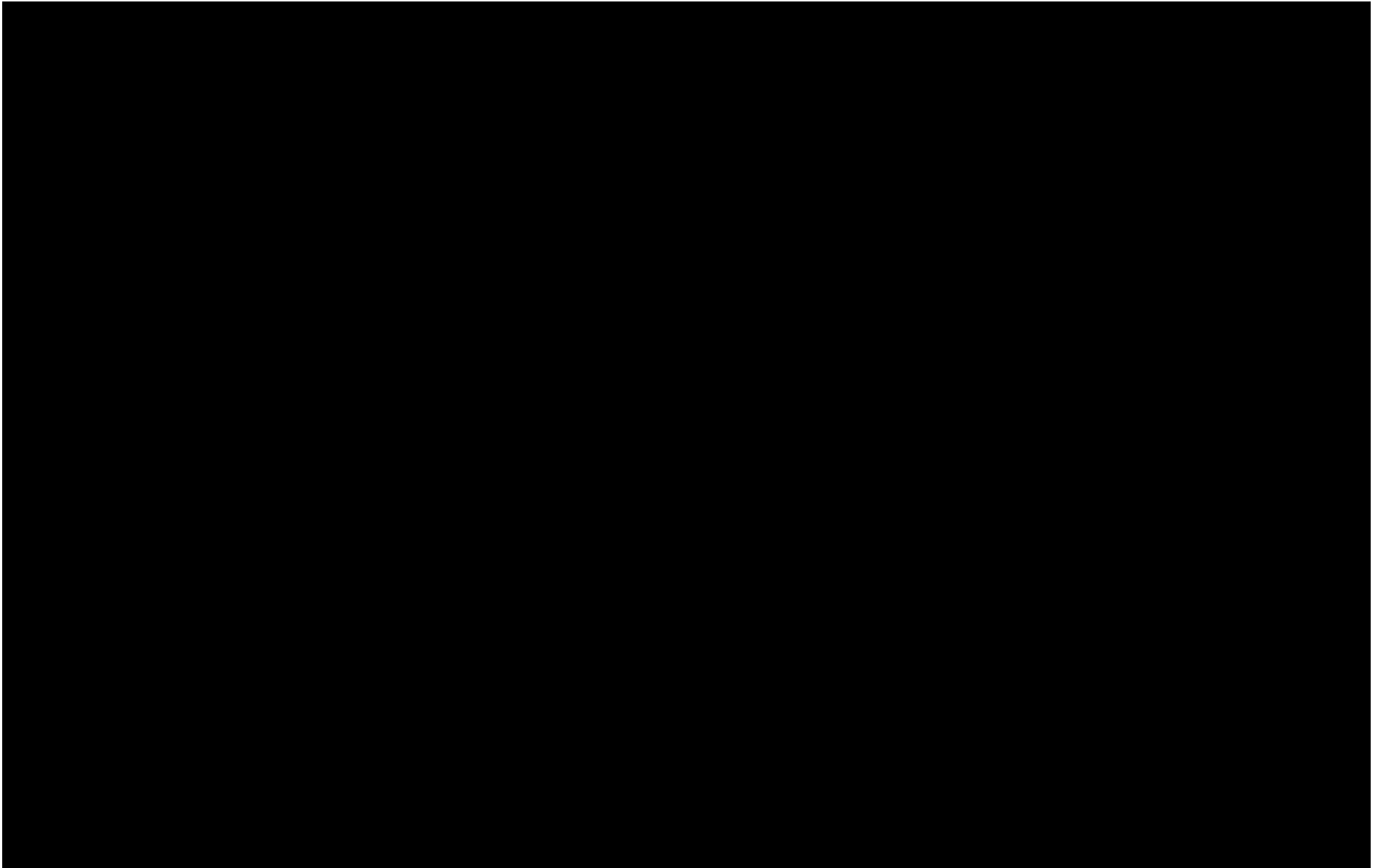
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**





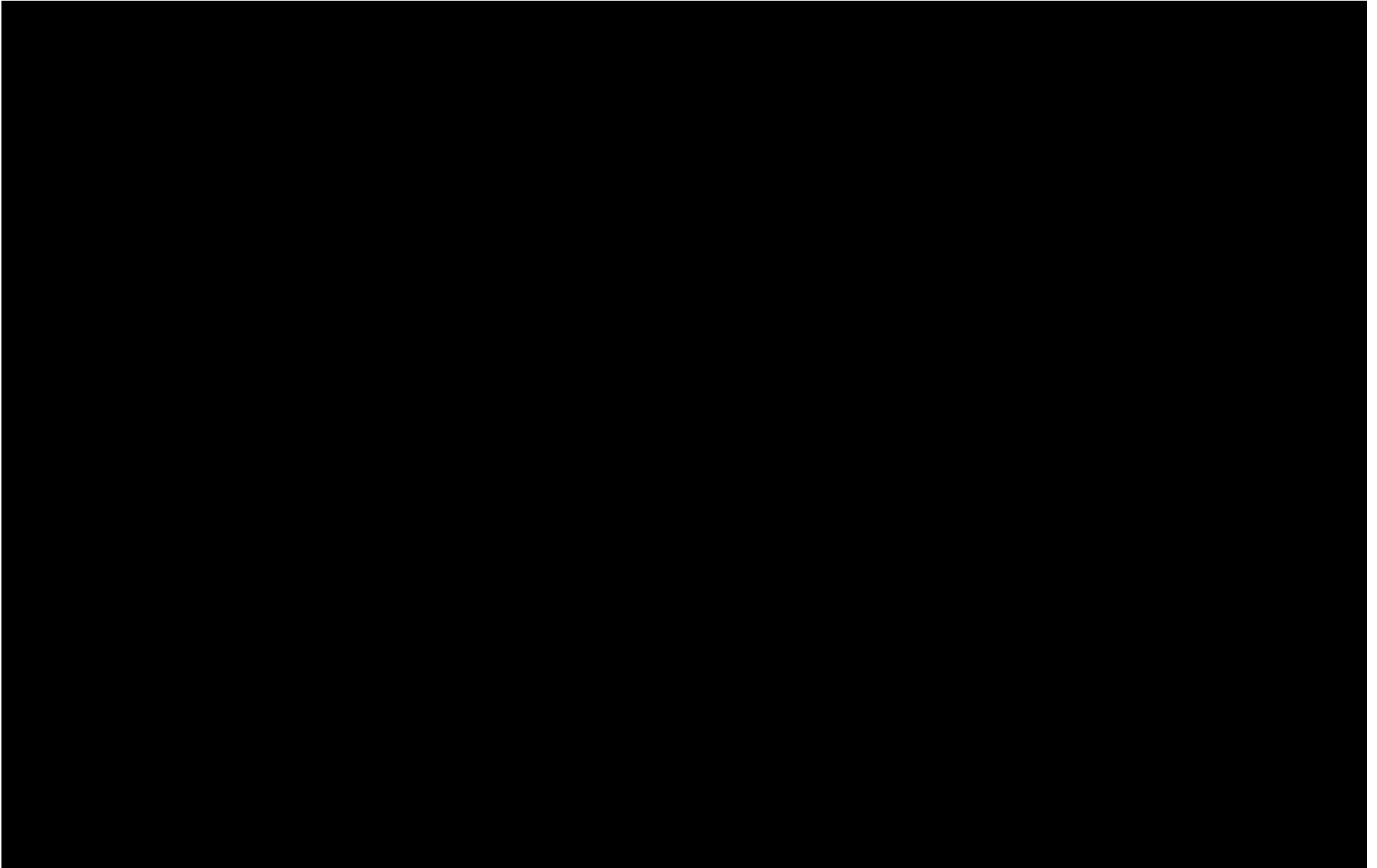
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



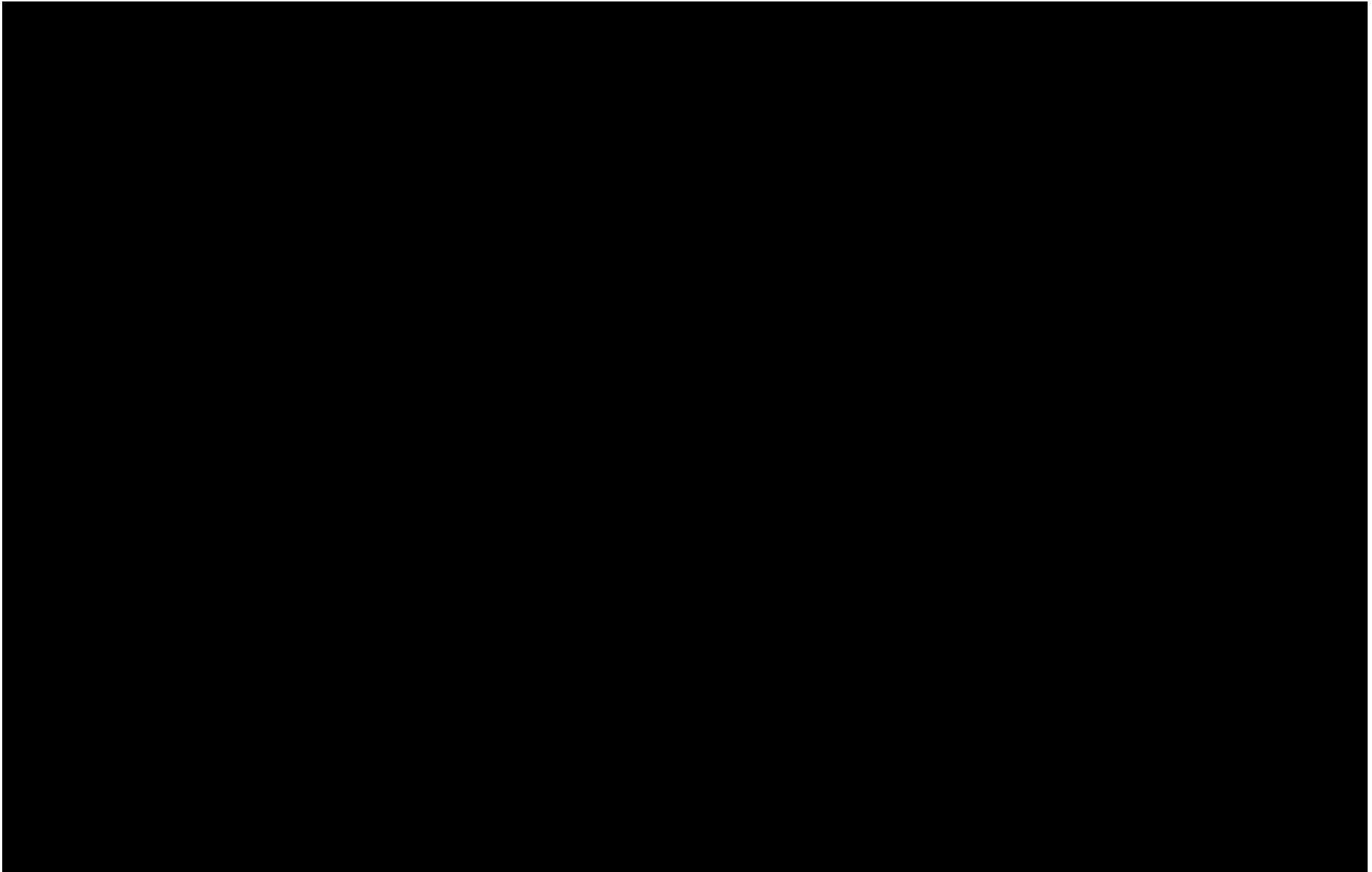
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



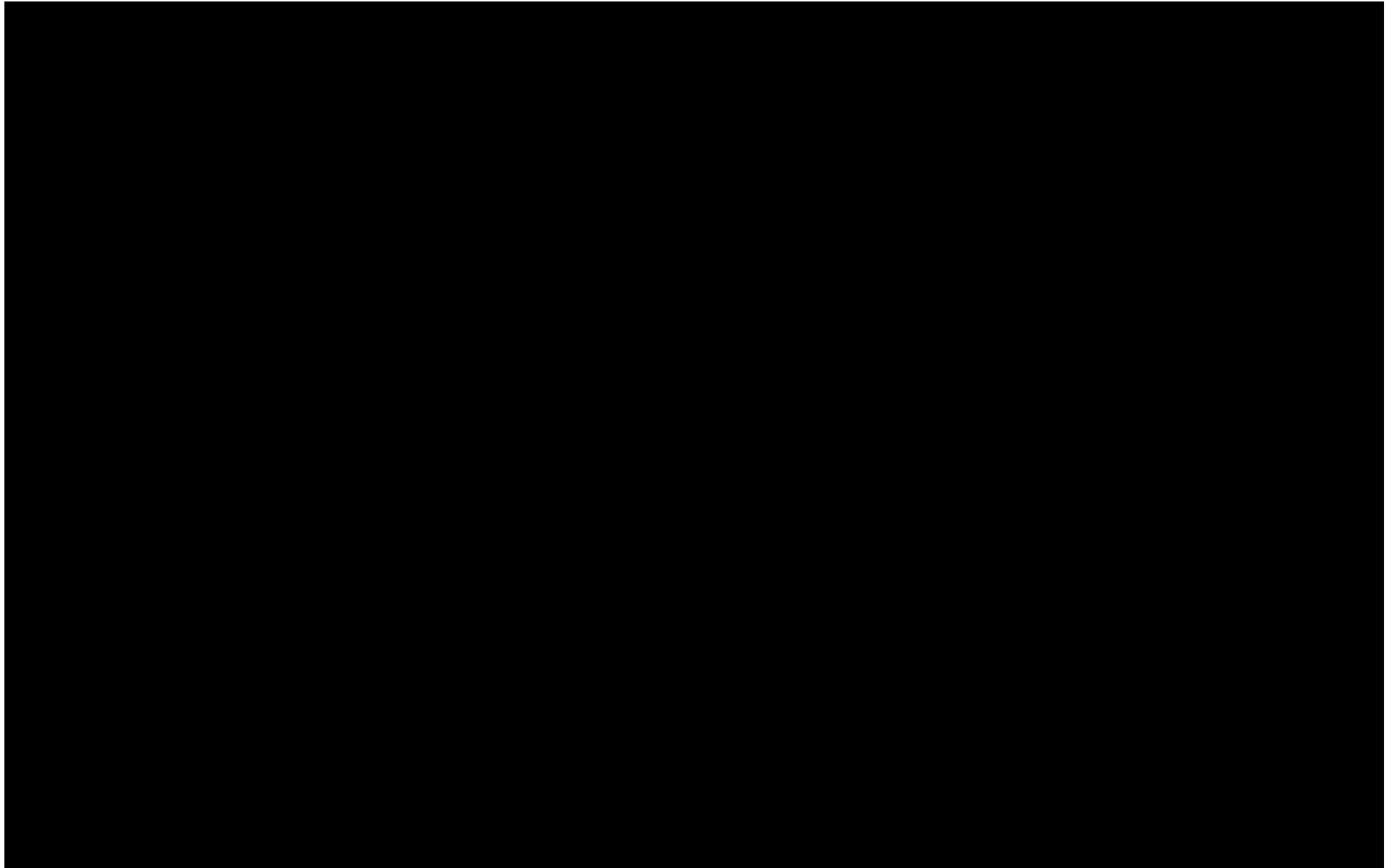
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**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



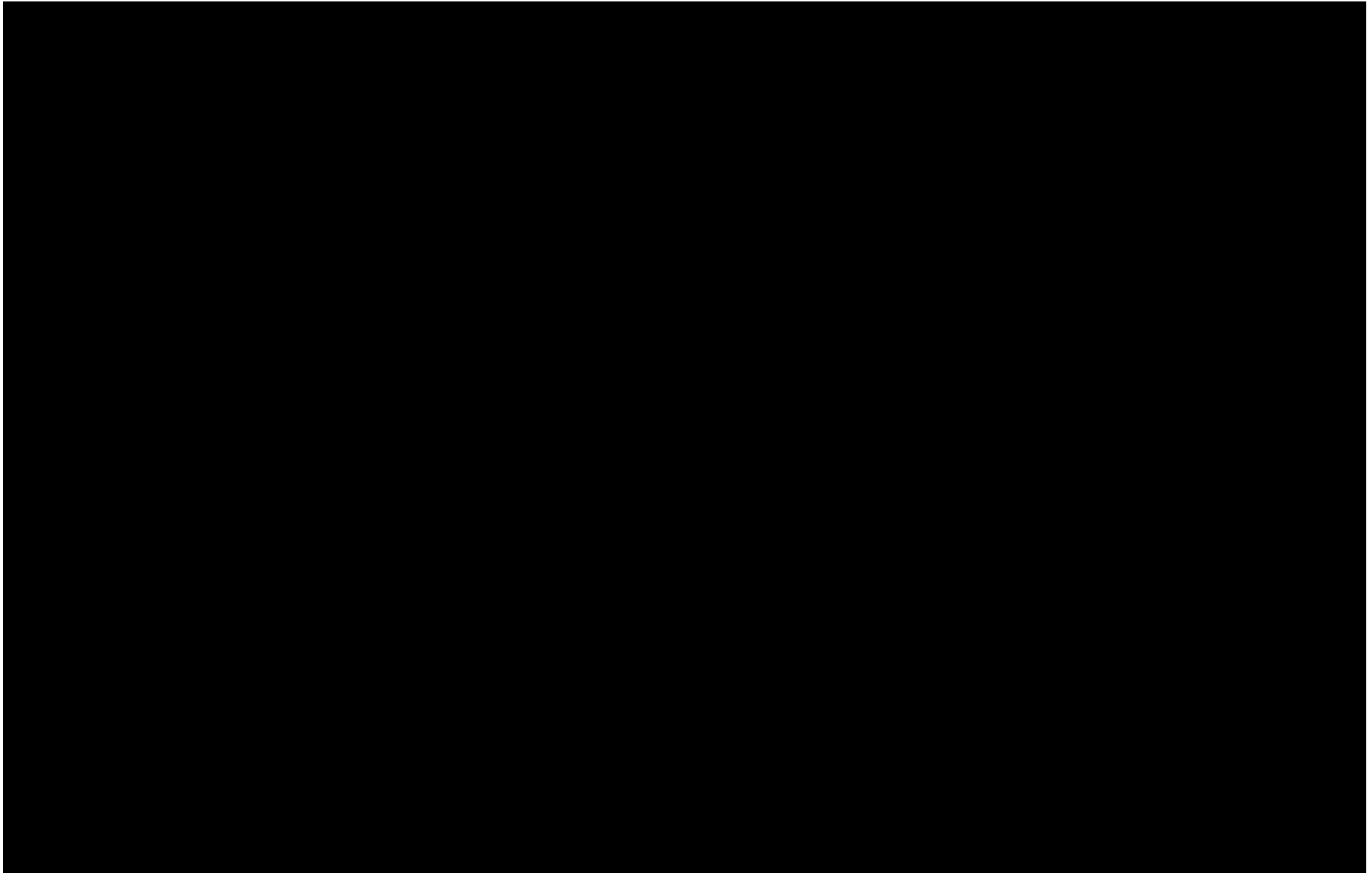
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**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



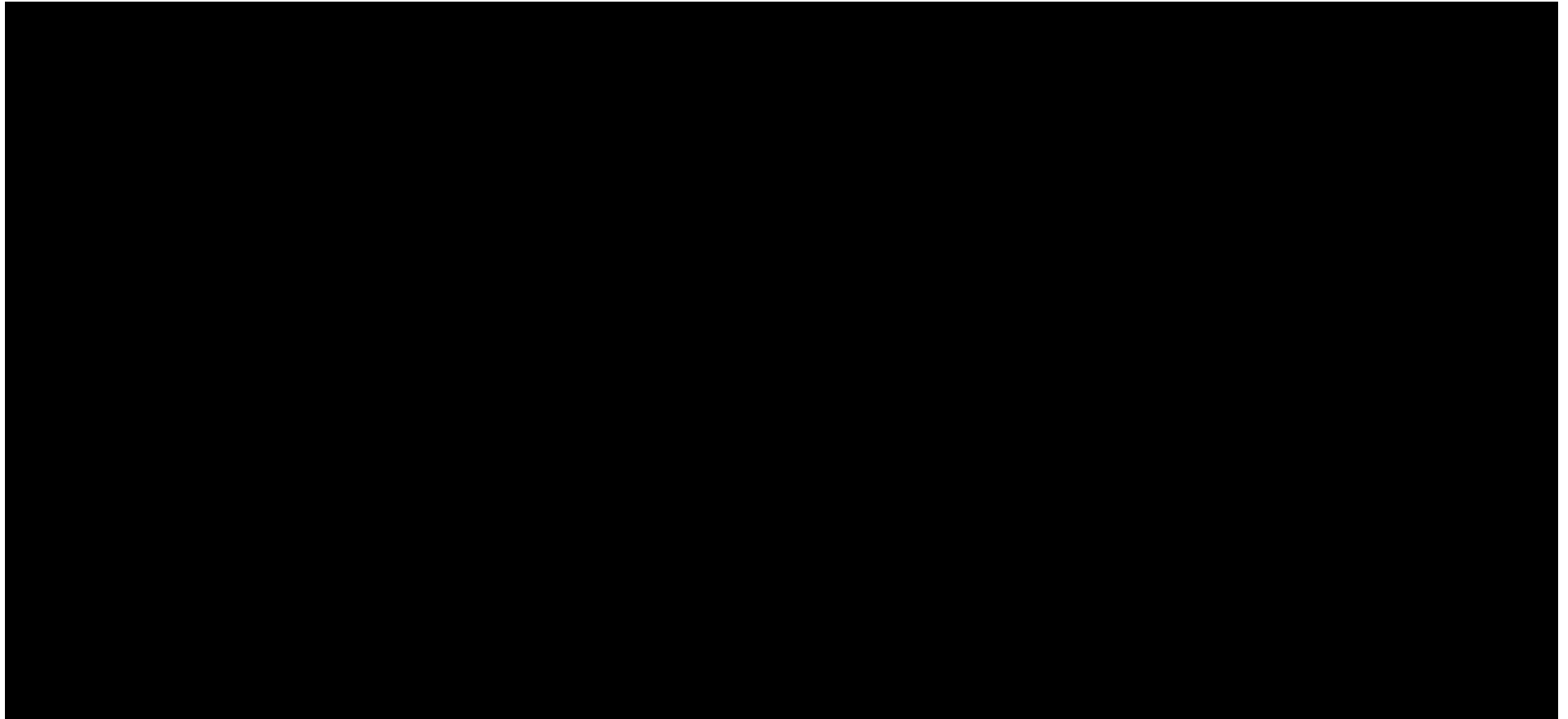
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

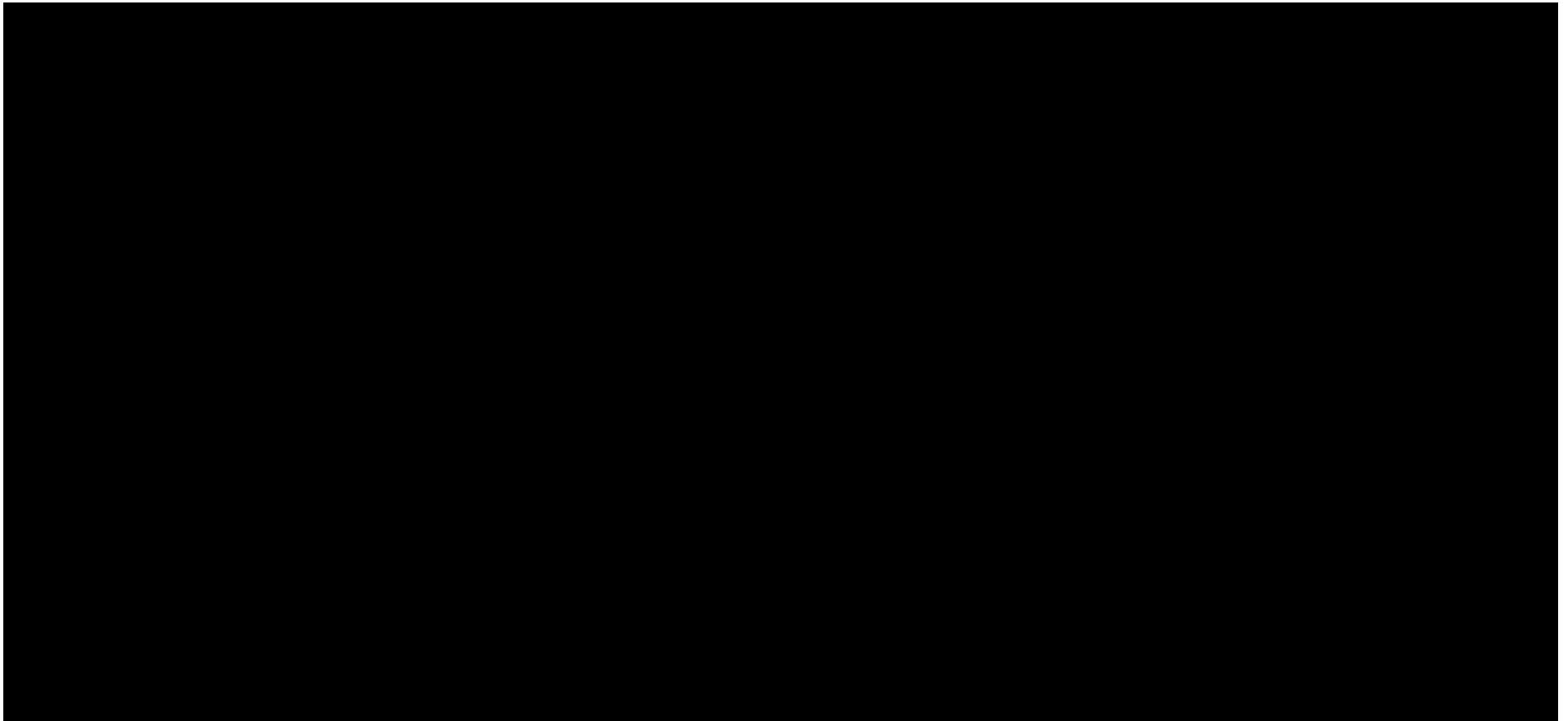
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

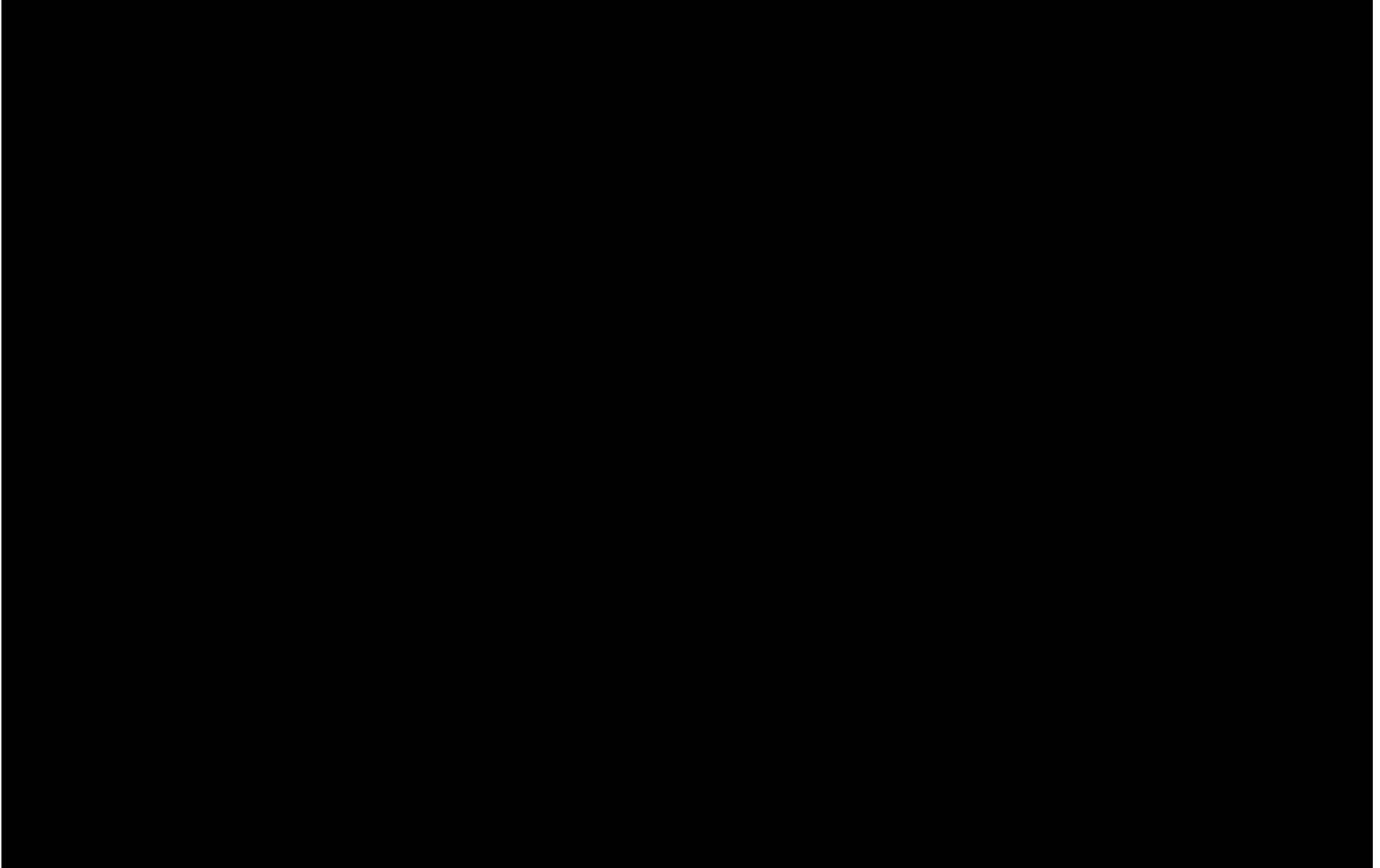
**DEFENDANTS’ NON-INFRINGEMENT CONTENTION CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”) for**  
**Linagliptin and Metformin, 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages**  
**in Abbreviated New Drug Application (“ANDA”) No. and 208336 (“the HEC ANDA”)**

Subject to the foregoing, Defendants provide in good faith the following non-infringement contentions for the asserted claims of the ’927 patent. Defendants reserve the right to amend their non-infringement contentions to take into account any information provided during discovery and the Court’s claim construction (if any) for terms recited in the claims of this patent. Because Plaintiffs have yet to produce the samples of JENTADUETO<sup>®</sup>, Defendants are unable to provide full and complete non-infringement contentions concerning the ’927 patent and reserve all rights to do so.



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

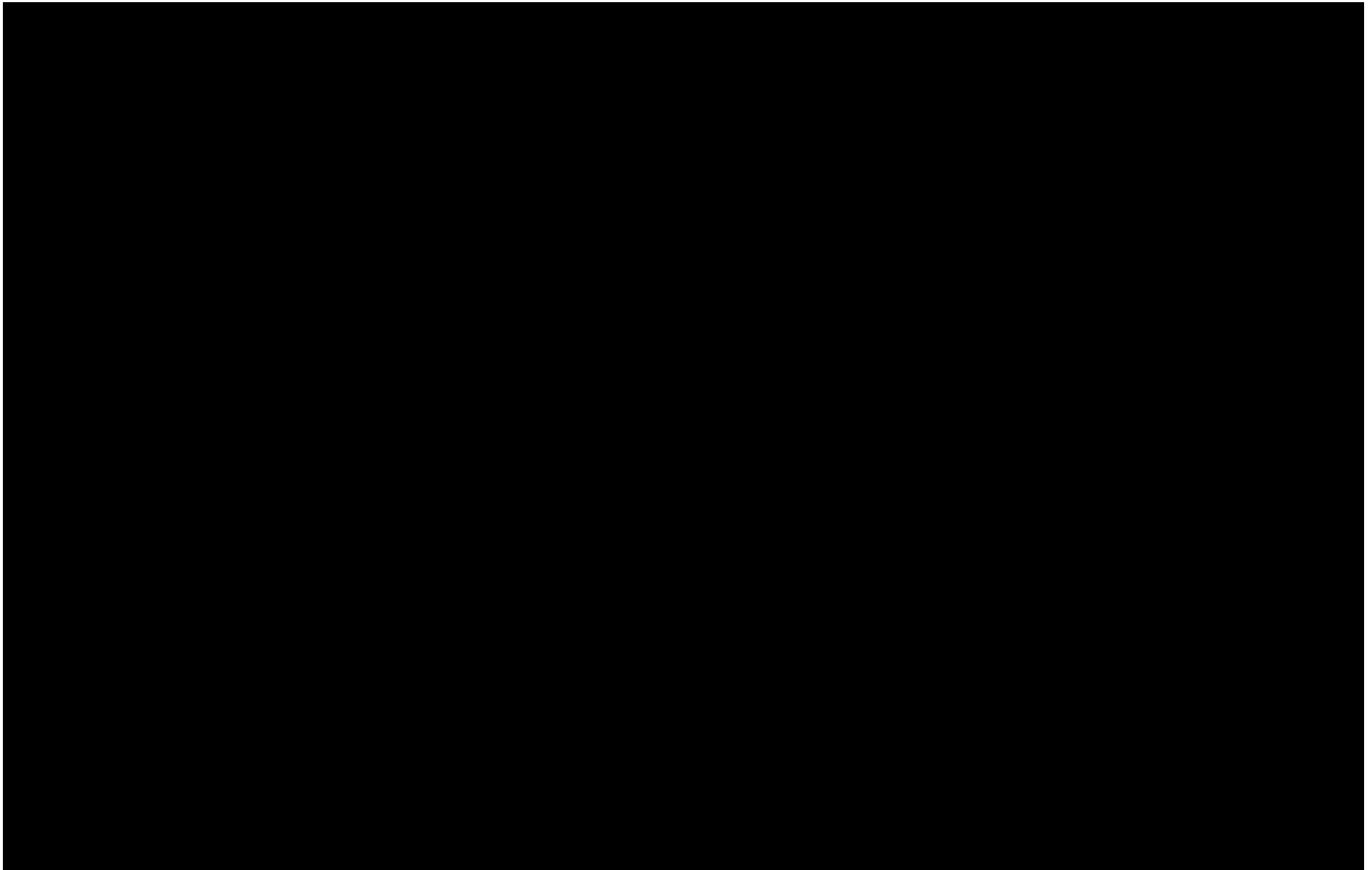
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**





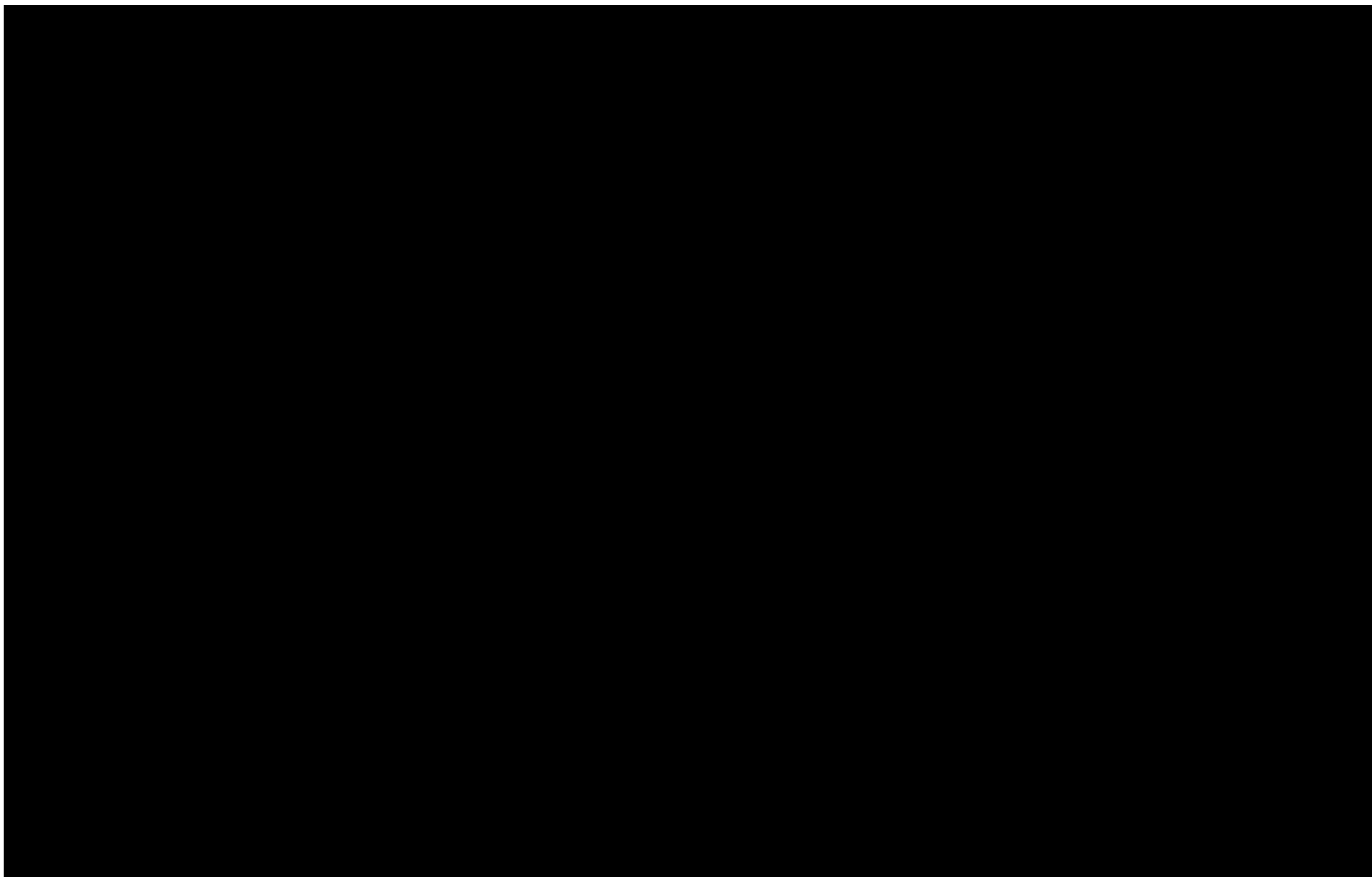
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



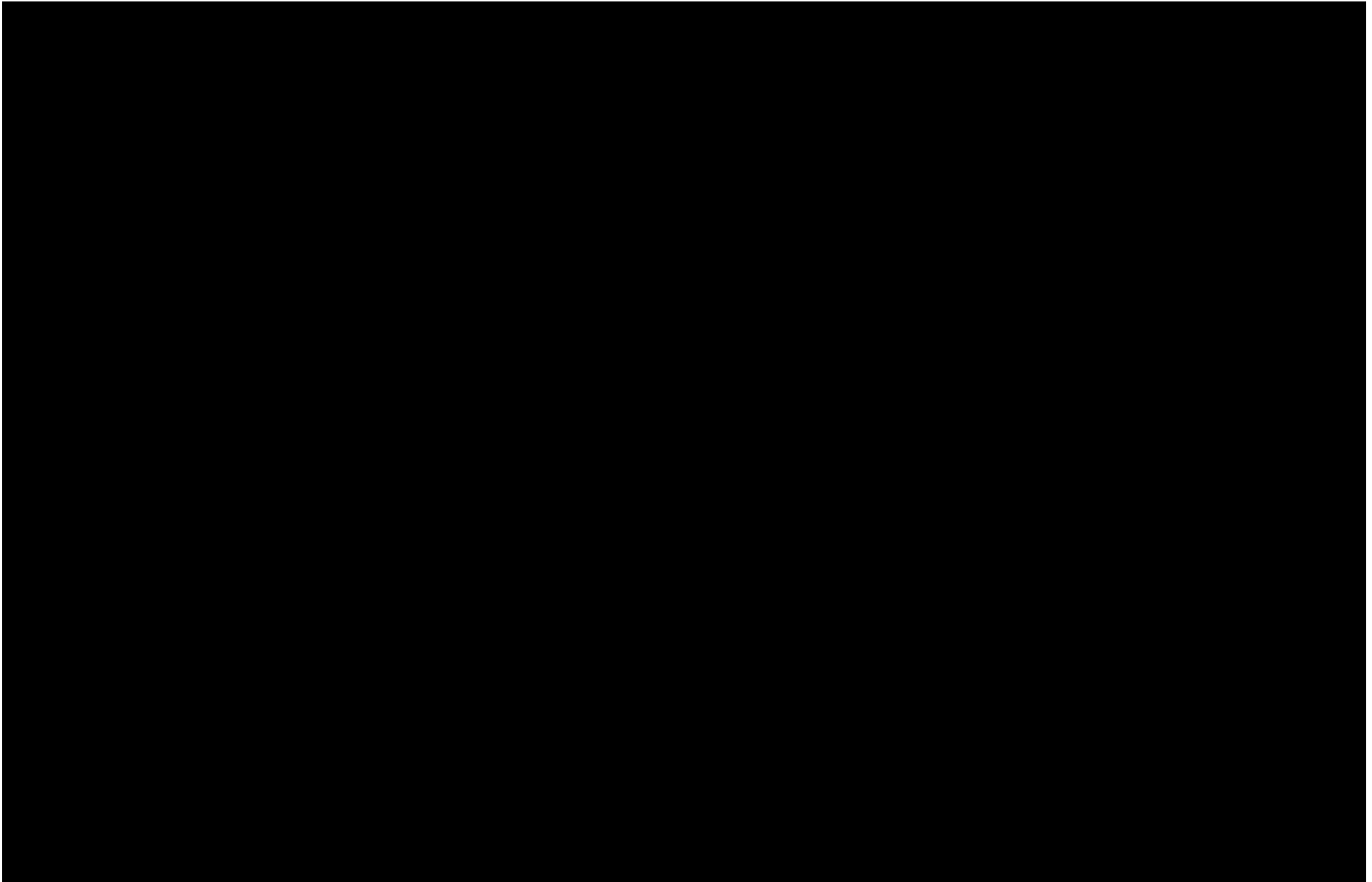
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



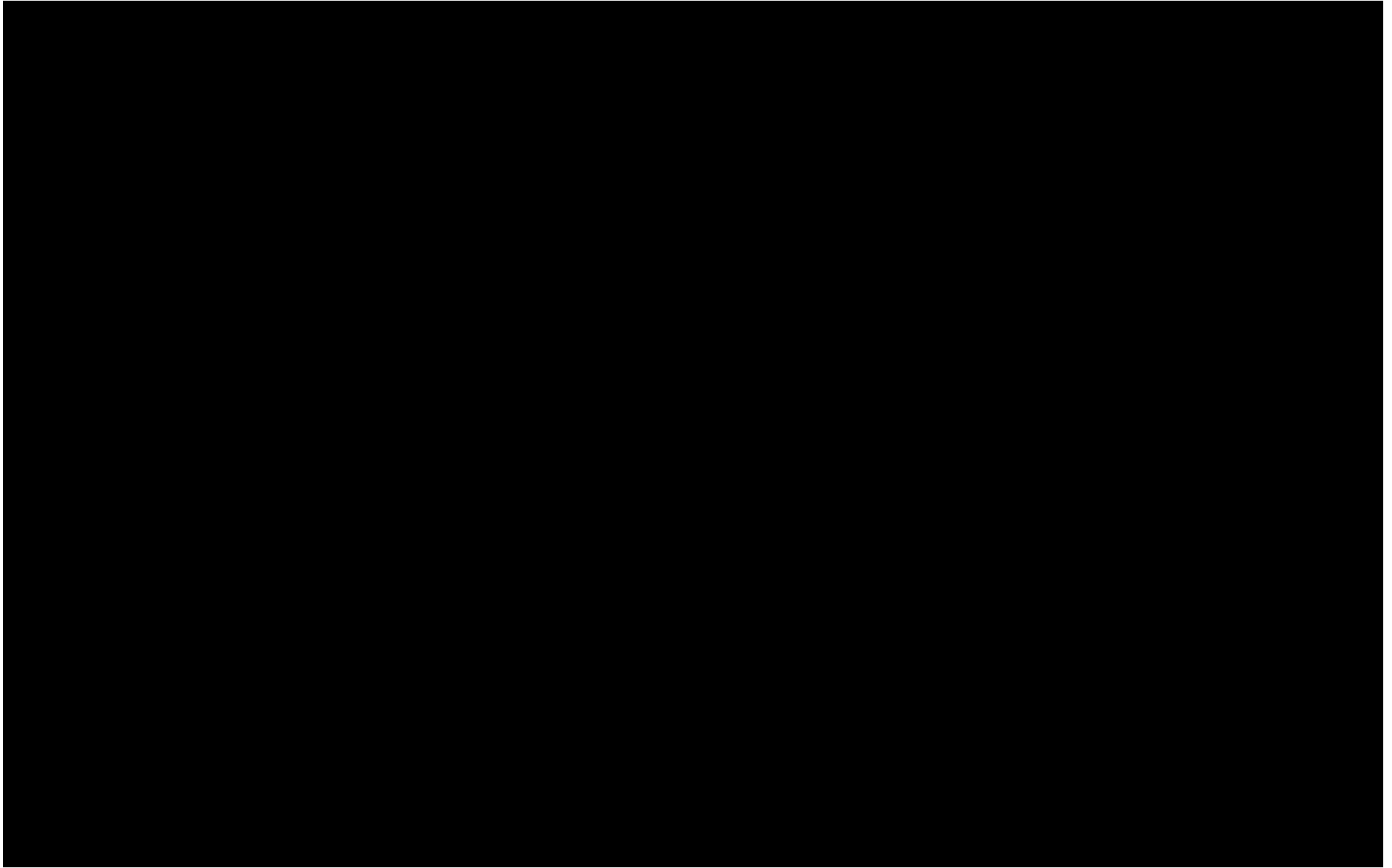
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



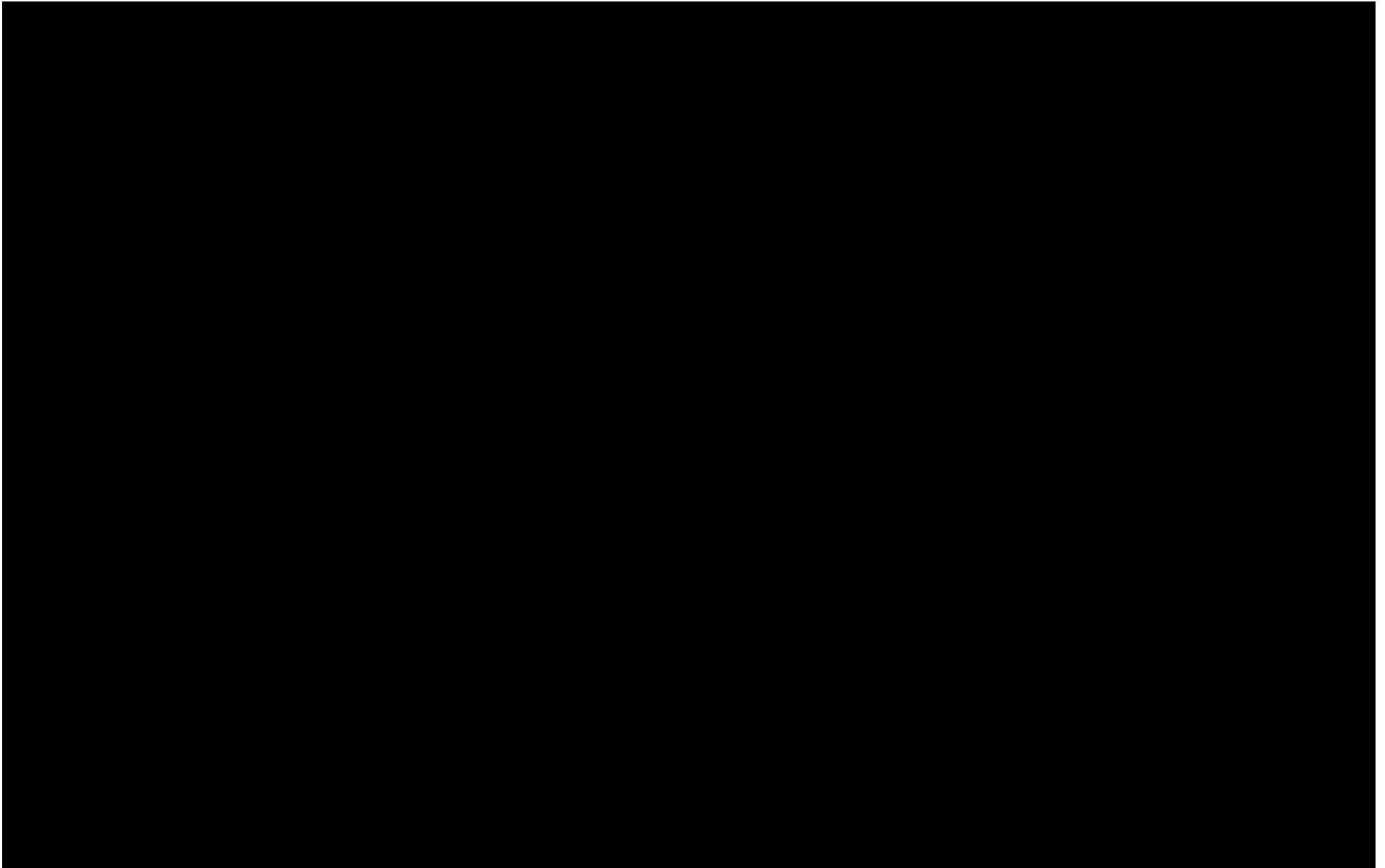
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



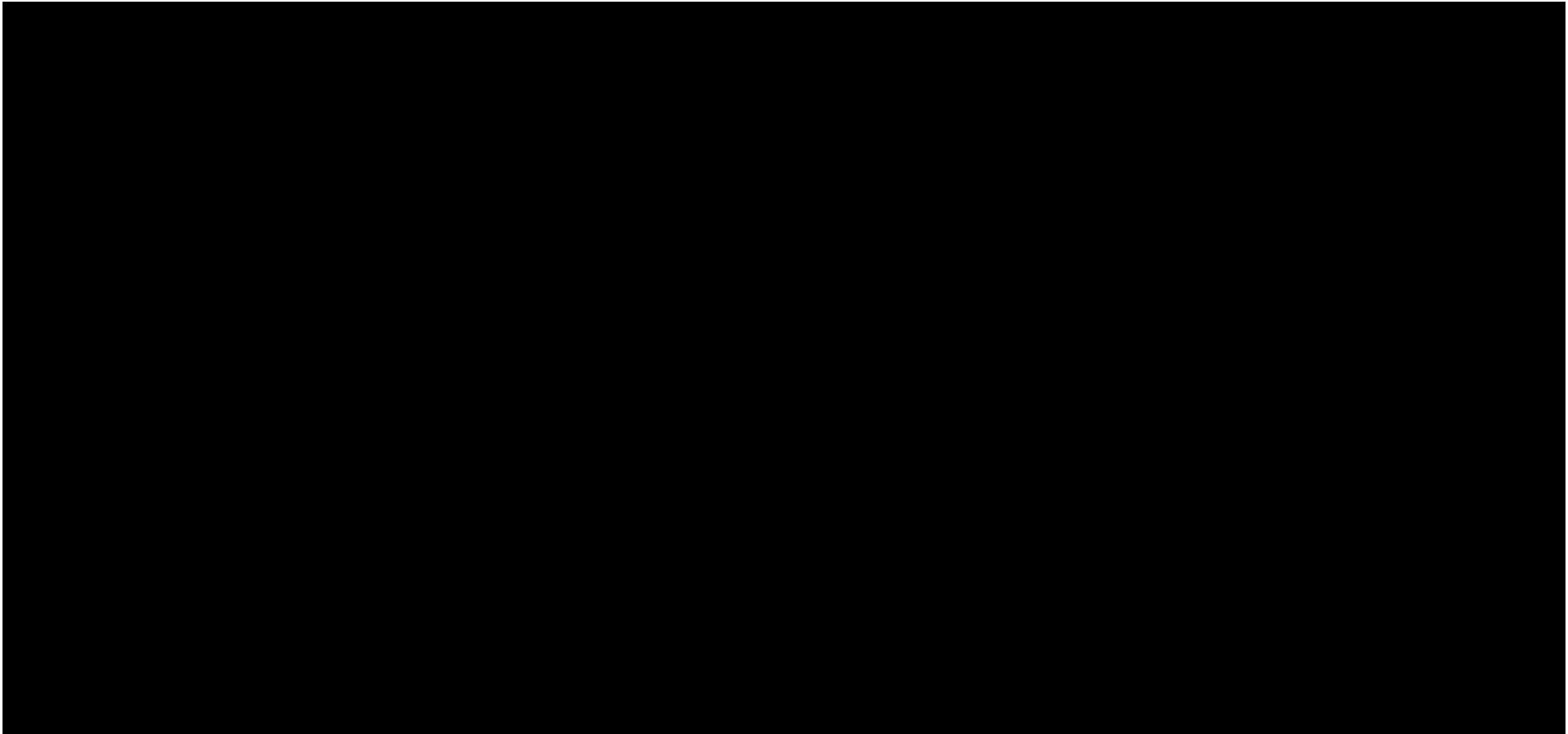
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

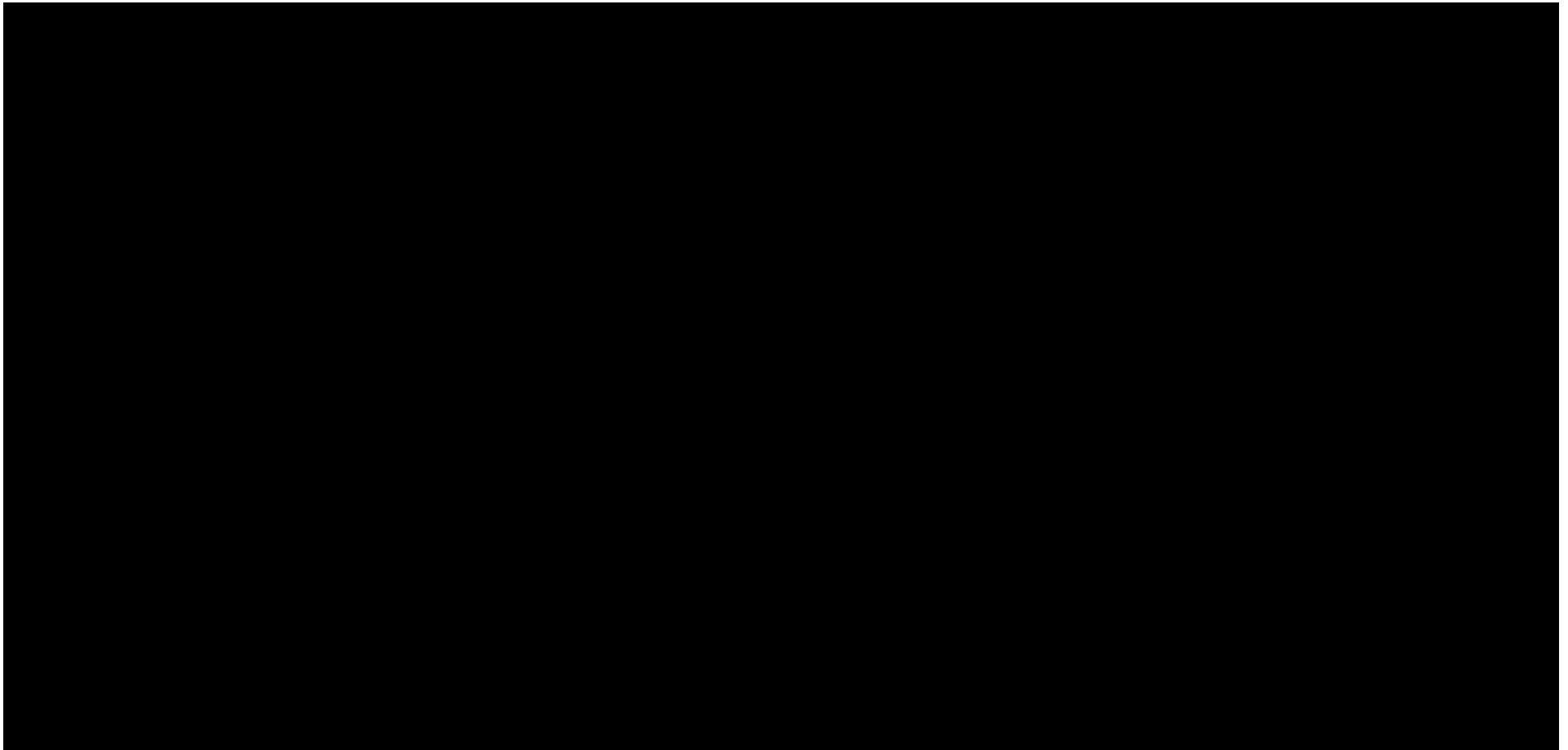
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,673,927 (“the ’927 Patent”)**



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

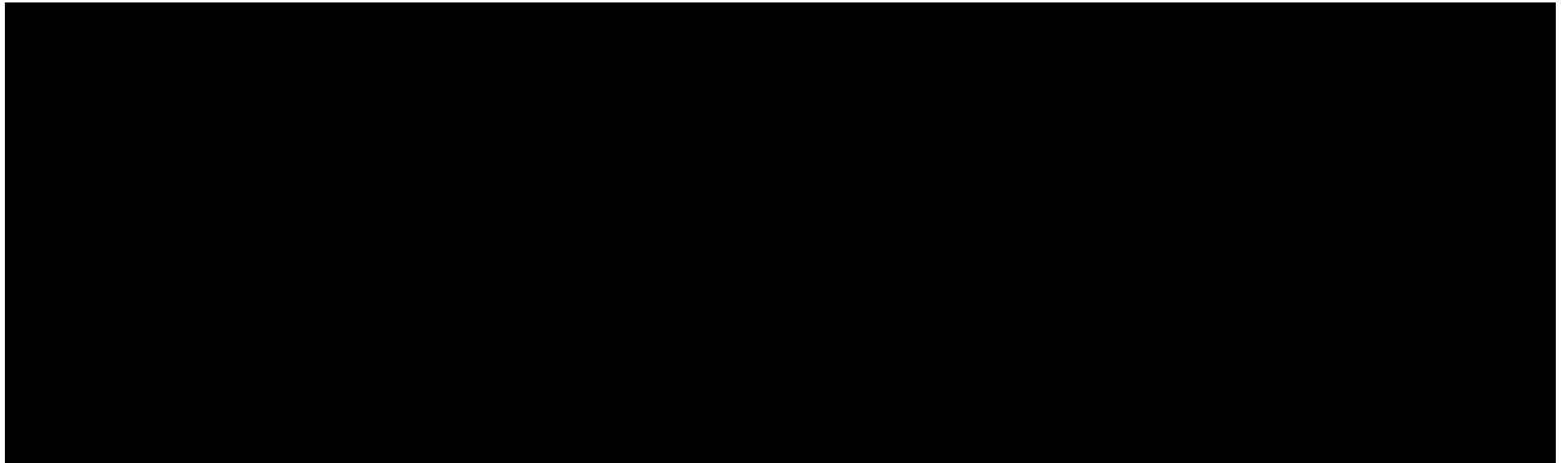
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,846,695 (“the ’695 Patent”) for Linagliptin, 0.5 mg dosage**  
**in Abbreviated New Drug Application (“ANDA”) No. 208335 (“the HEC ANDA”)**

Subject to the foregoing, Defendants provide in good faith the following non-infringement contentions for the asserted claims of the ’695 patent. Defendants reserve the right to amend their non-infringement contentions to take into account any information provided during discovery and the Court’s claim construction (if any) for terms recited in the claims of this patent. Because Plaintiffs have yet to produce the samples of TRADJENTA<sup>®</sup>, Defendants are unable to provide full and complete non-infringement contentions concerning the ’695 patent and reserve all rights to do so.



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,846,695 (“the ’695 Patent”)**

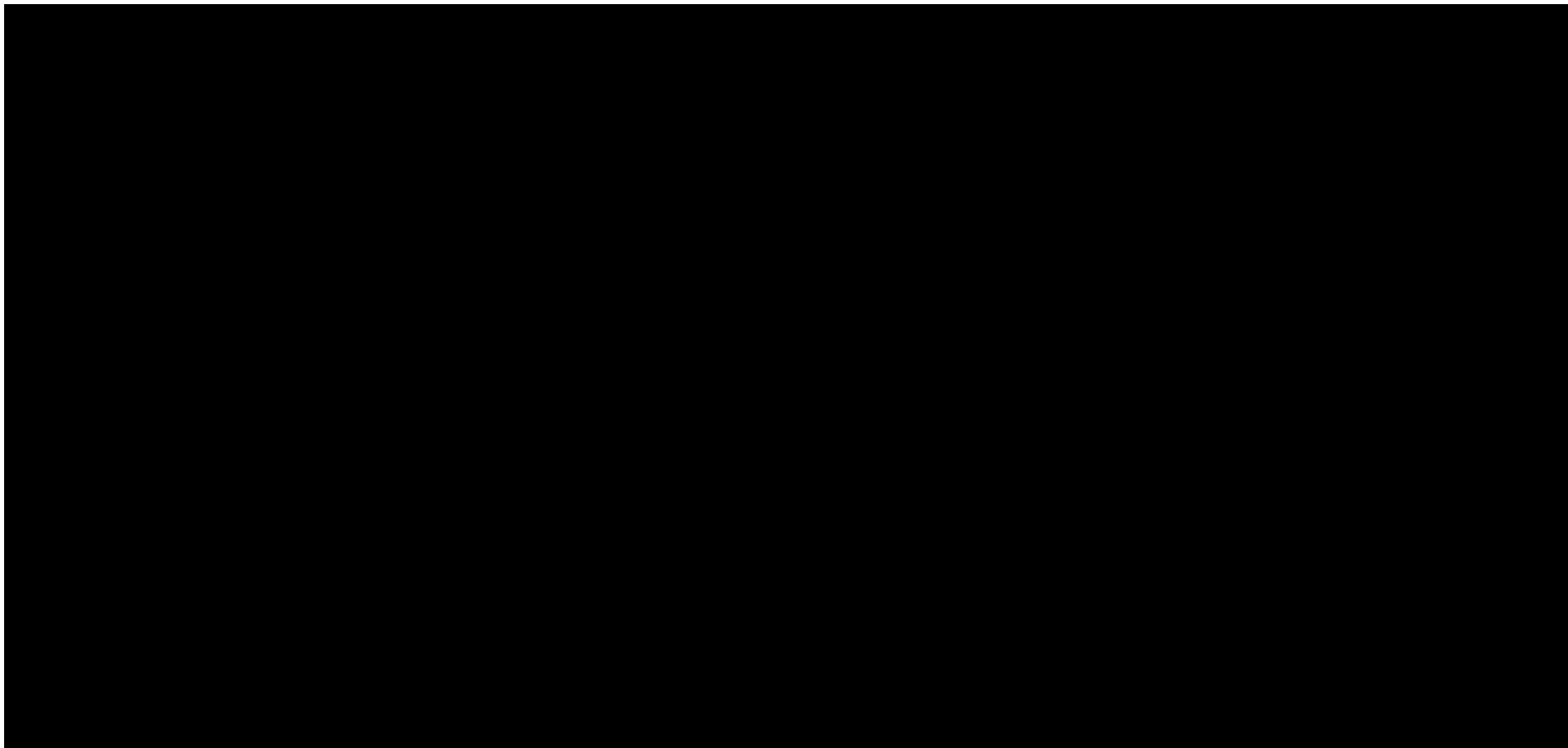




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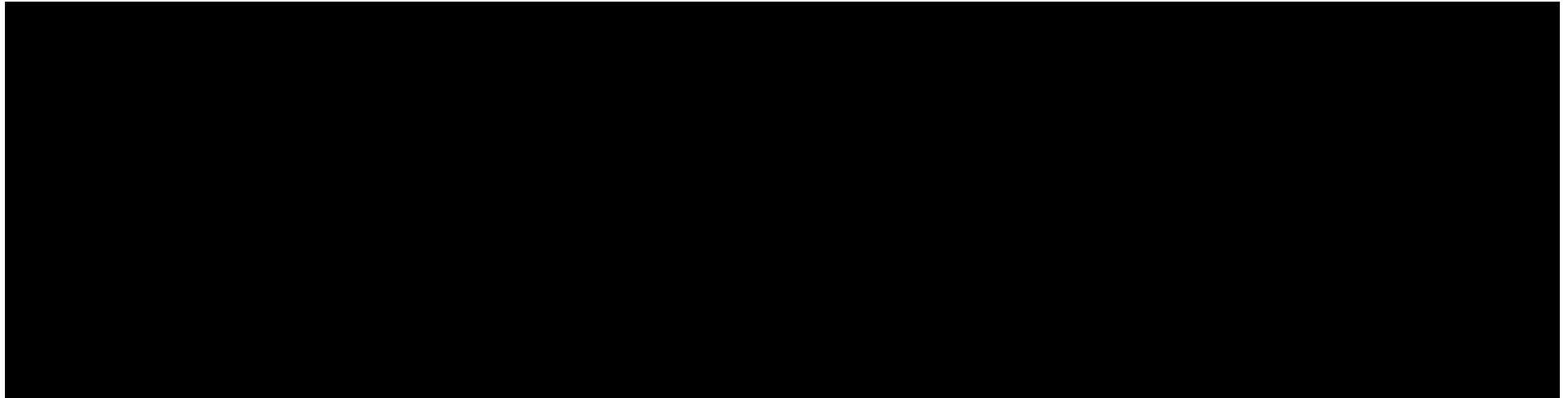
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,846,695 (“the ’695 Patent”) for**  
**Linagliptin and Metformin, 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages**  
**in Abbreviated New Drug Application (“ANDA”) No. and 208336 (“the HEC ANDA”)**

Subject to the foregoing, Defendants provide in good faith the following non-infringement contentions for the asserted claims of the ’695 patent. Defendants reserve the right to amend their non-infringement contentions to take into account any information provided during discovery and the Court’s claim construction (if any) for terms recited in the claims of this patent. Because Plaintiffs have yet to produce the samples of JENTADUETO<sup>®</sup>, Defendants are unable to provide full and complete non-infringement contentions concerning the ’695 patent and reserve all rights to do so.



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

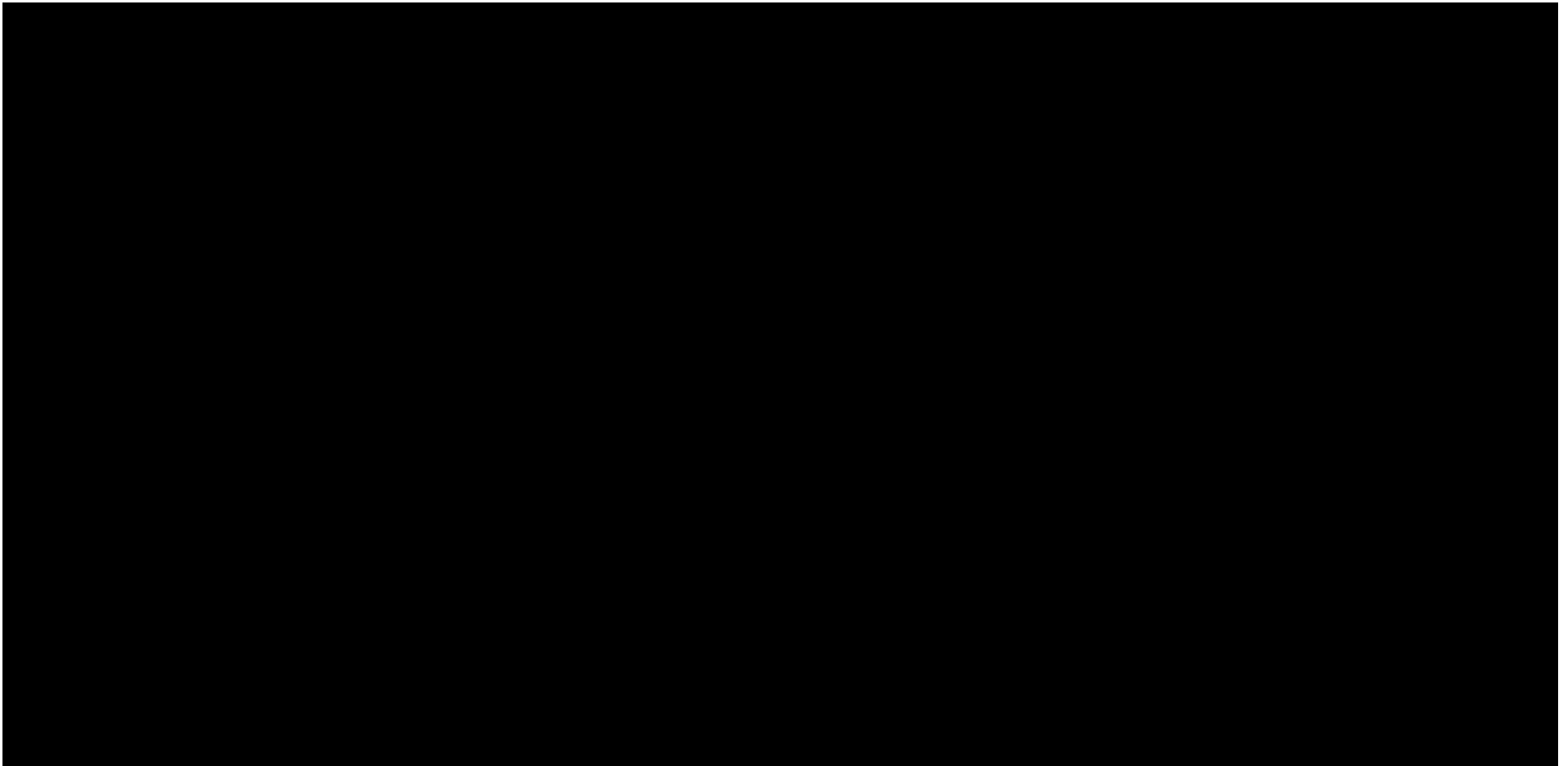
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,846,695 (“the ’695 Patent”)**



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

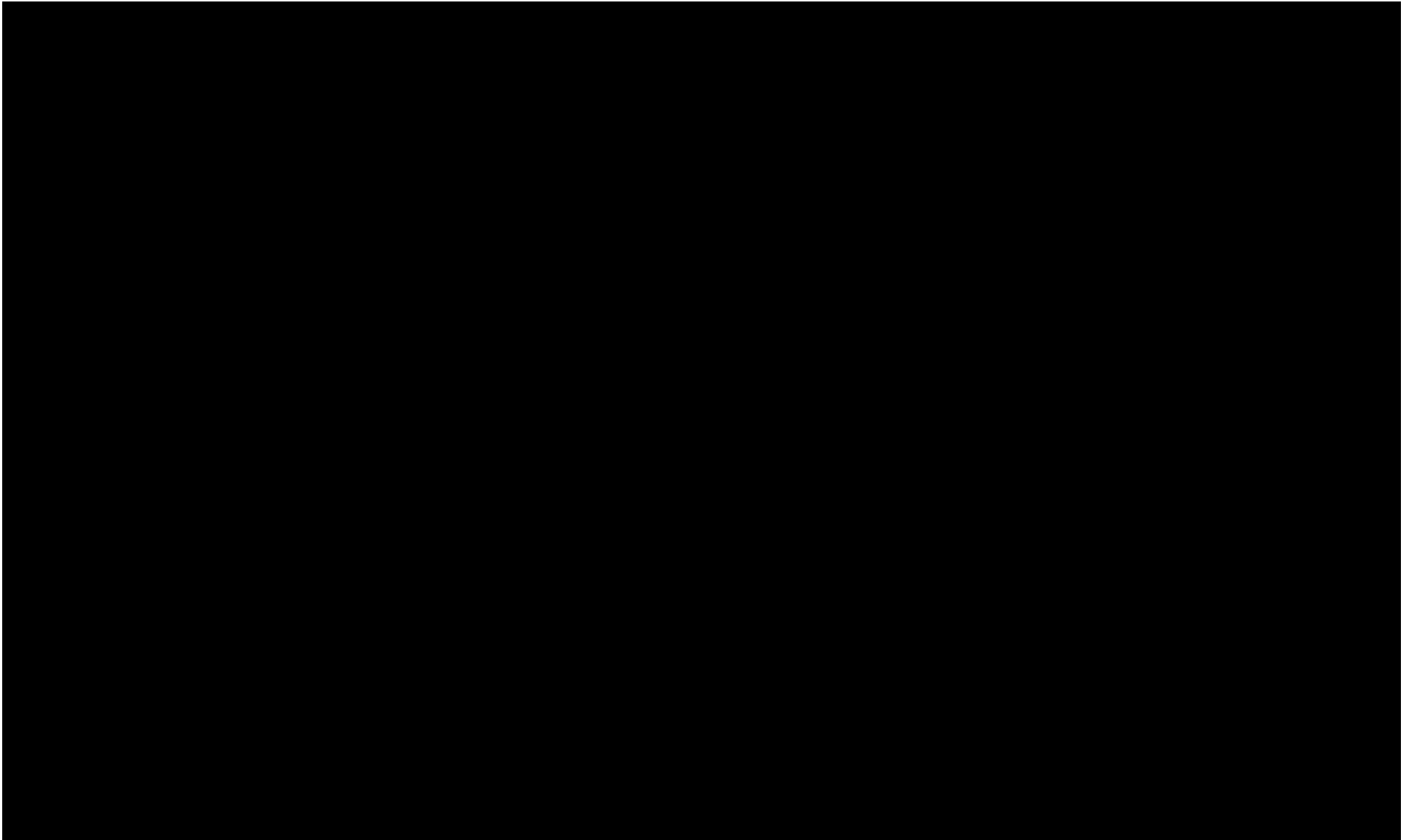
**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,853,156 (“the ’156 Patent”) for Linagliptin, 0.5 mg dosage**  
**in Abbreviated New Drug Application (“ANDA”) No. 208335 (“the HEC ANDA”)**

Subject to the foregoing, Defendants provide in good faith the following non-infringement contentions for the asserted claims of the ’156 patent. Defendants reserve the right to amend their non-infringement contentions to take into account any information provided during discovery and the Court’s claim construction (if any) for terms recited in the claims of this patent. Because Plaintiffs have yet to produce the samples of TRADJENTA<sup>®</sup>, Defendants are unable to provide full and complete non-infringement contentions concerning the ’156 patent and reserve all rights to do so.



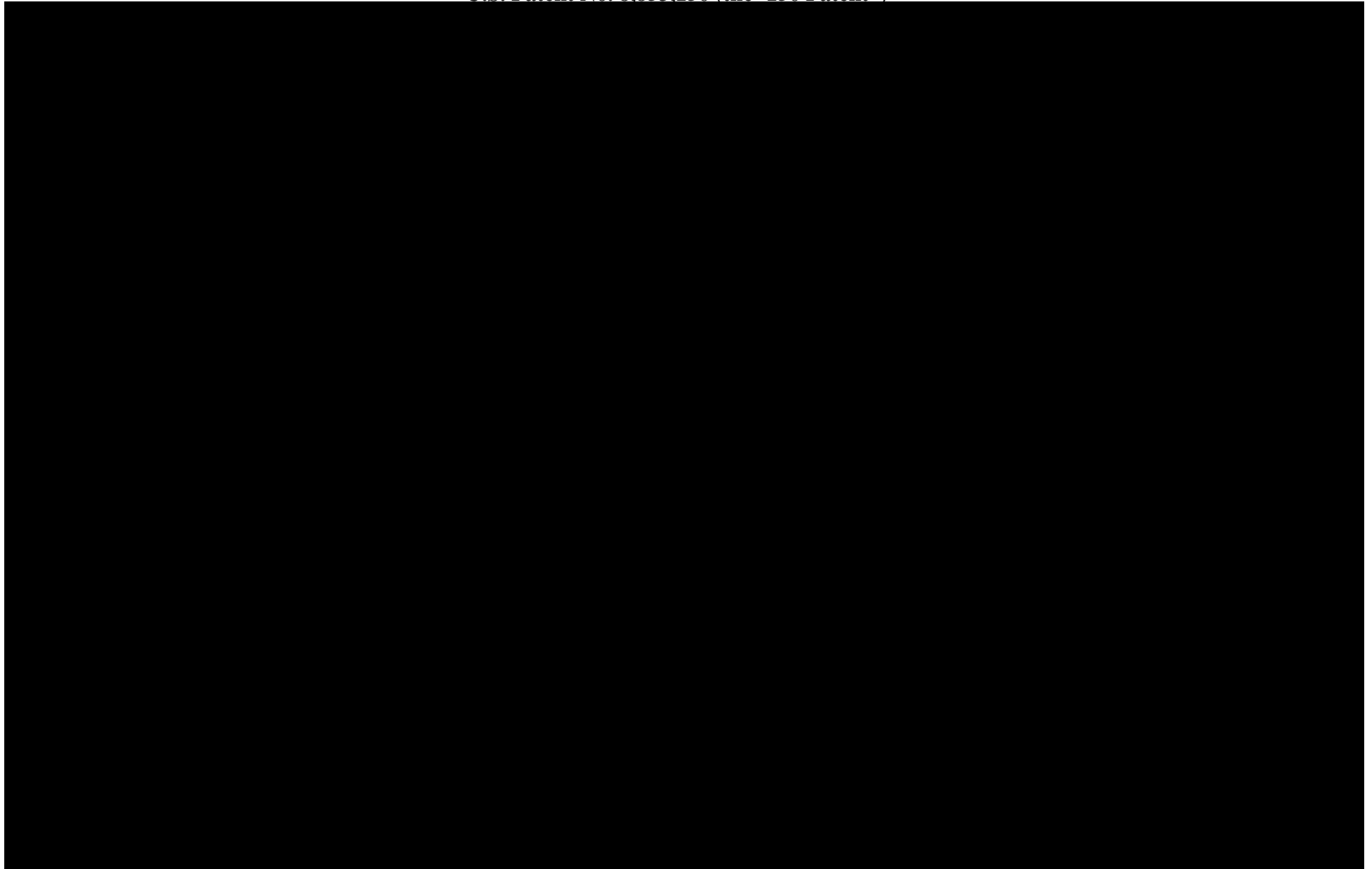
**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,853,156 (the ’156 Patent”)**



**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,853,156 (the ’156 Patent”)**

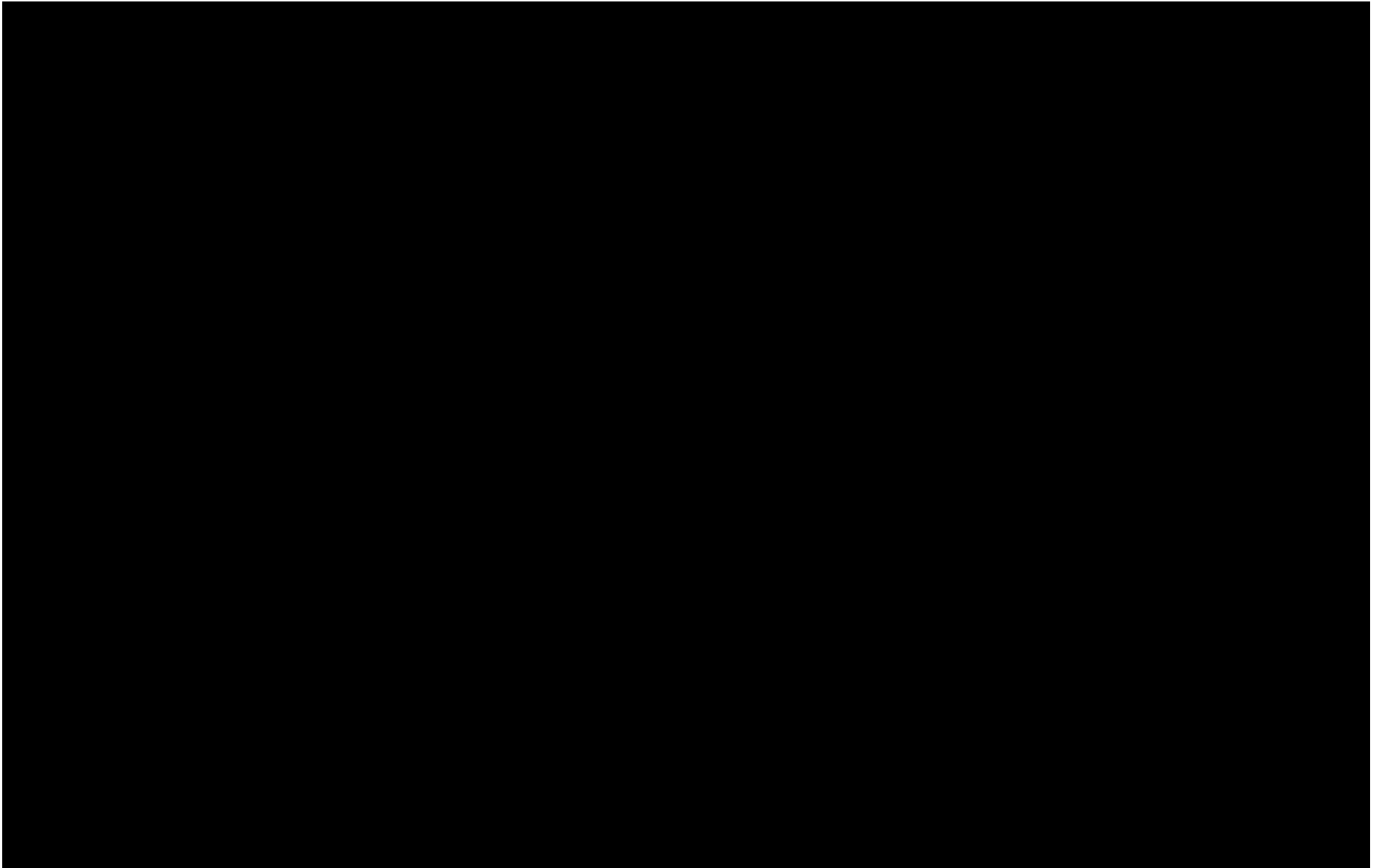


**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,853,156 (the ’156 Patent”)**

**HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY**

**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,853,156 (the ’156 Patent”)**



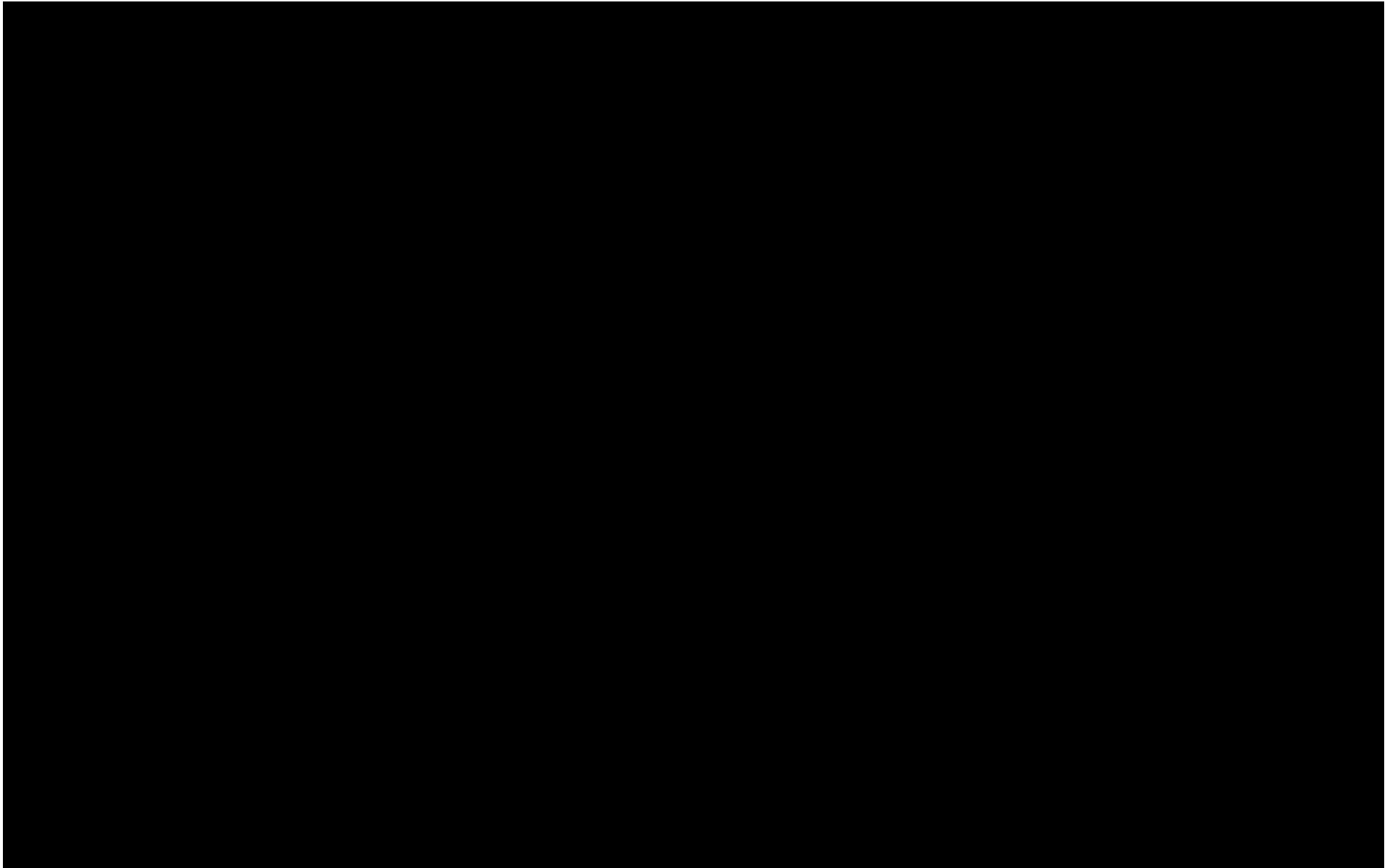
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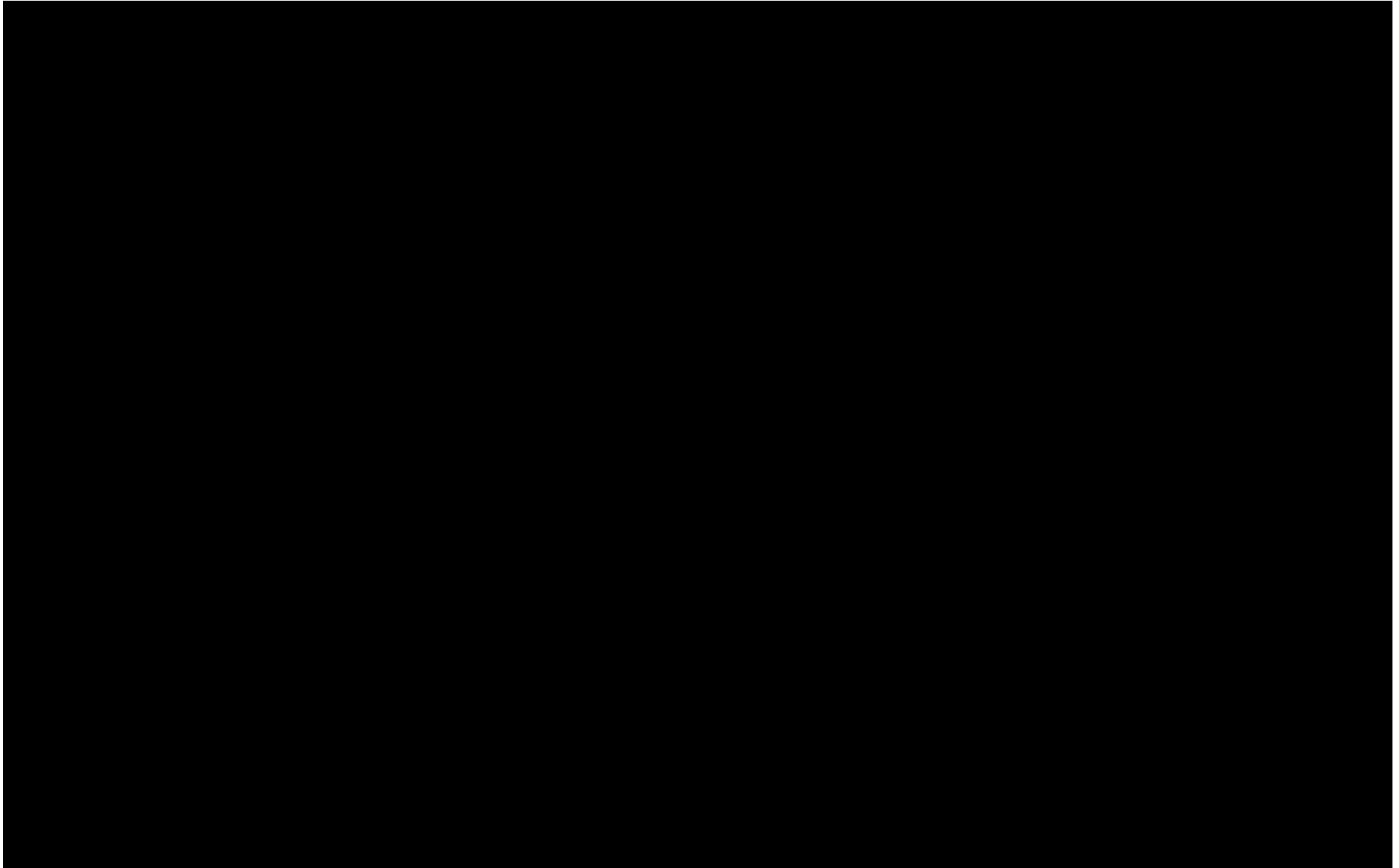
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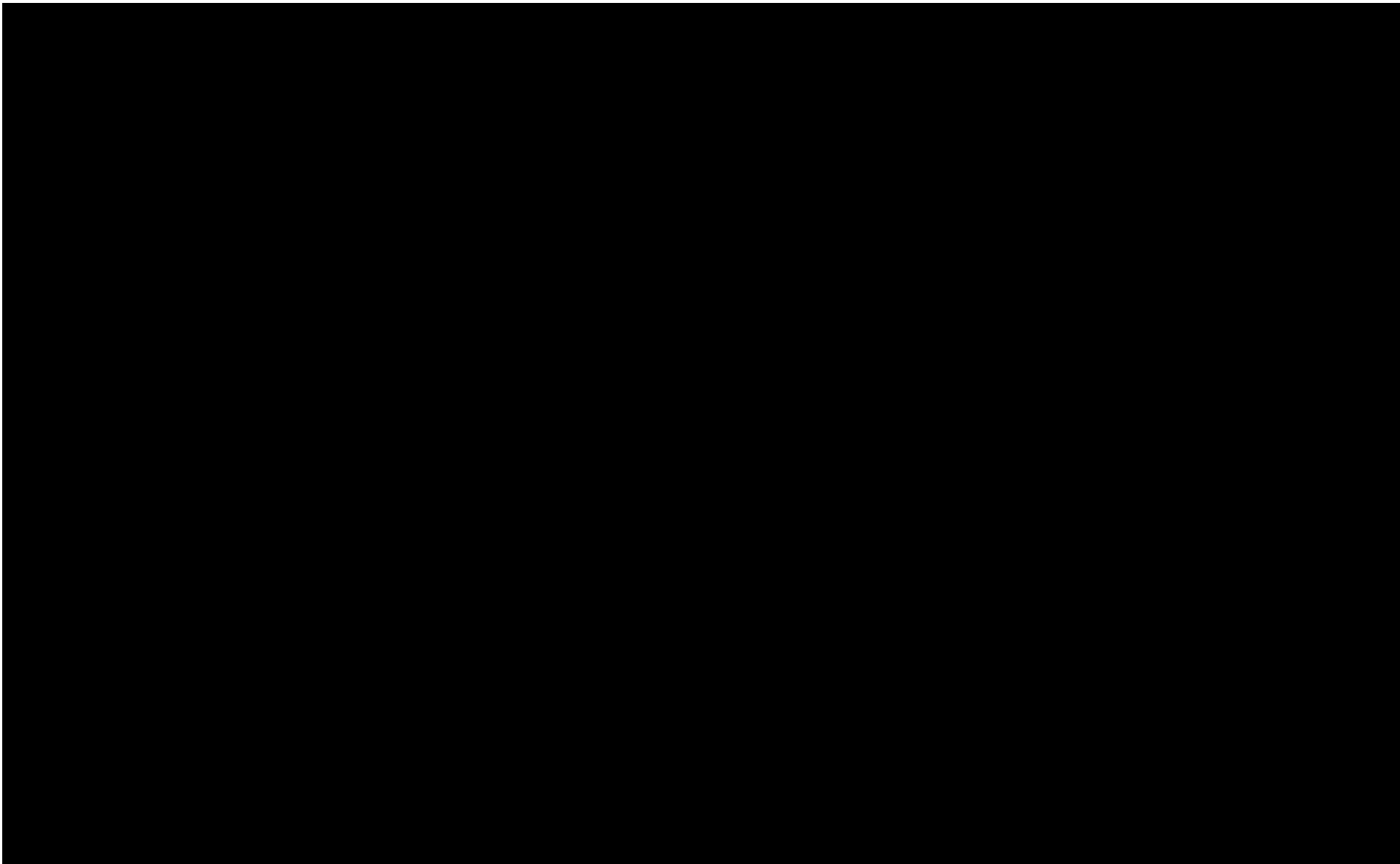
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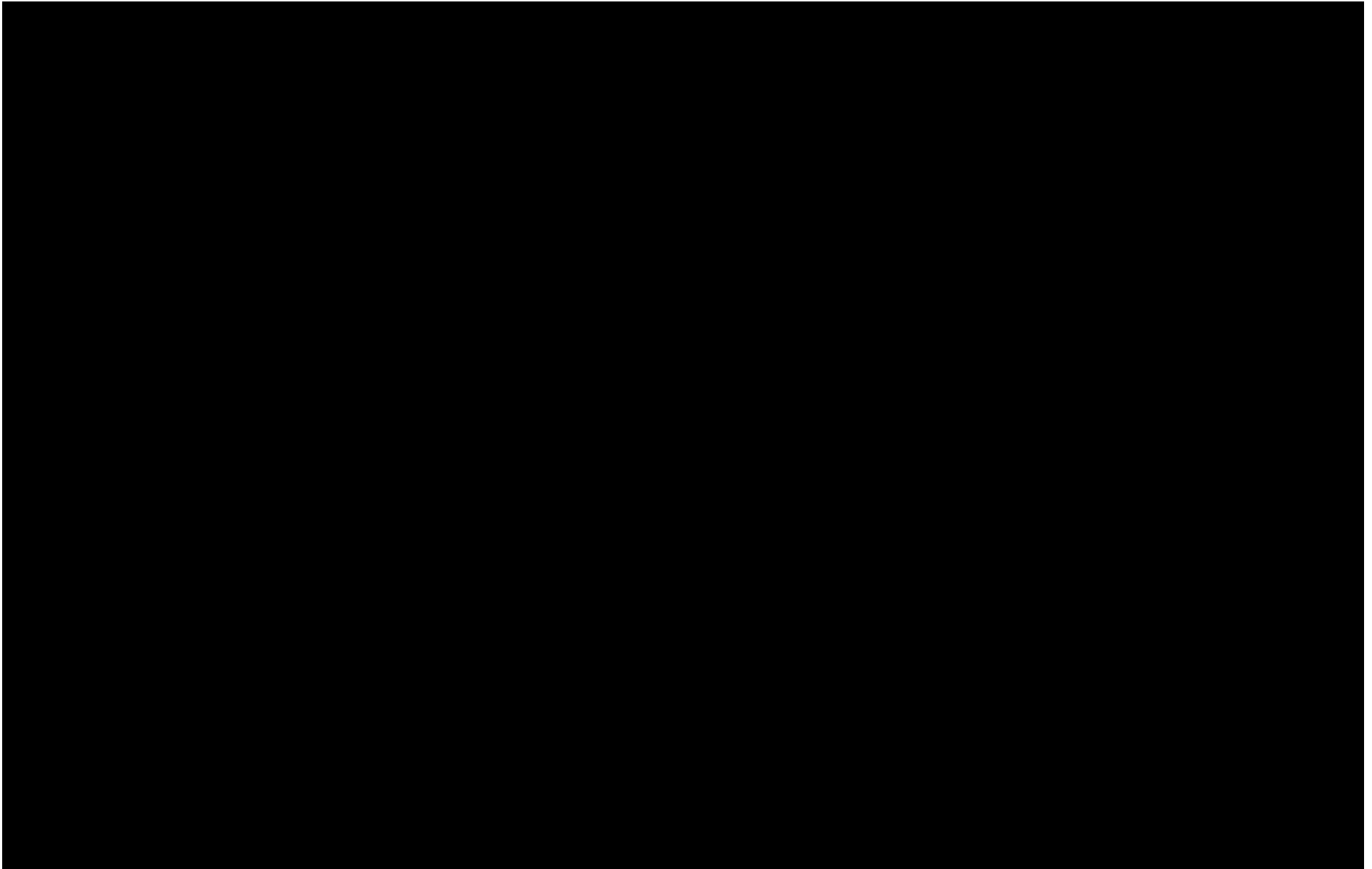
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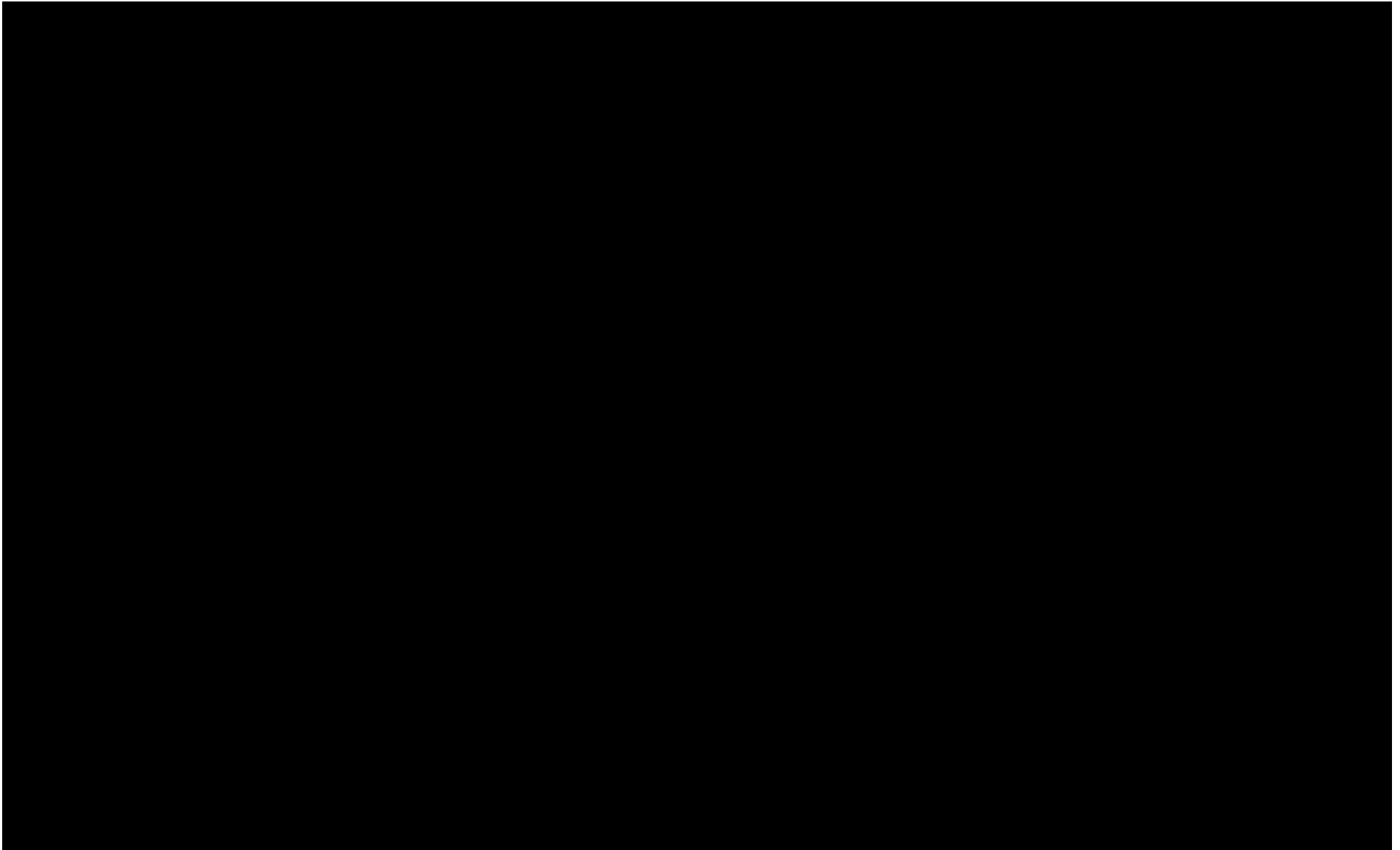
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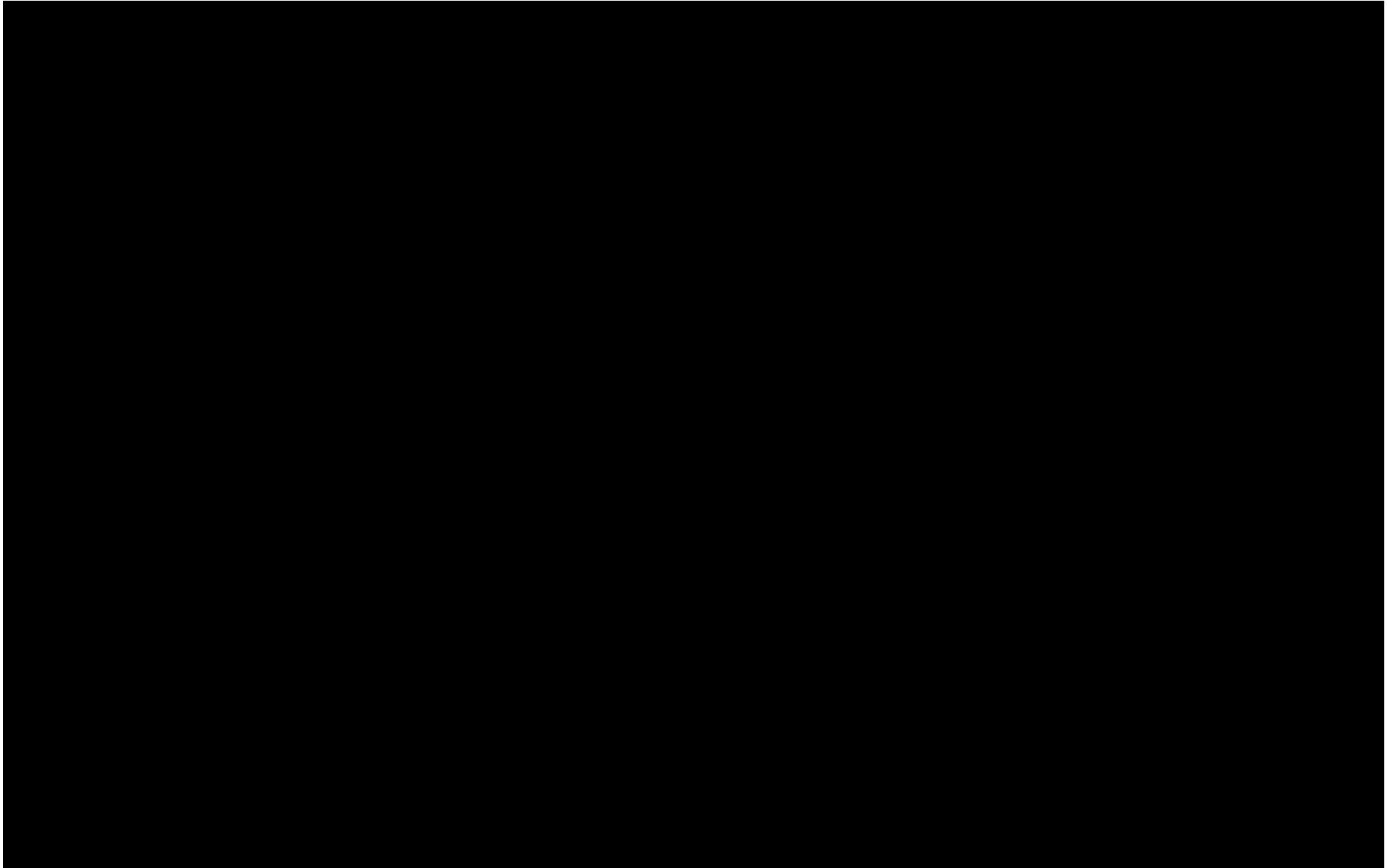
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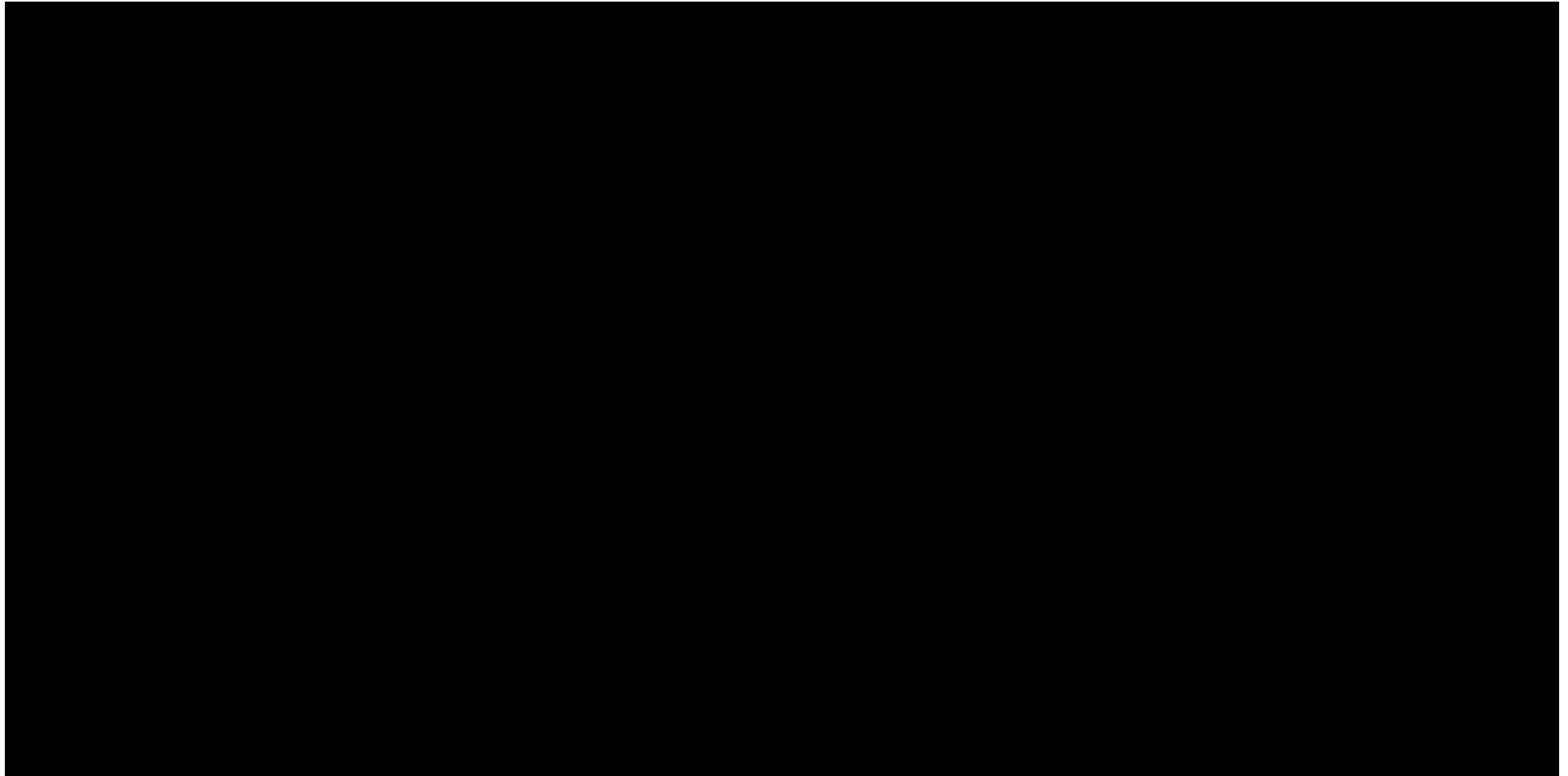
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**DEFENDANTS’ NON-INFRINGEMENT CONTENTIONS CLAIM CHART**  
**U.S. Patent No. 8,853,156 (the ’156 Patent”)**



# **EXHIBIT 5**

## **FILED UNDER SEAL**



HIGHLY CONFIDENTIAL – Rebuttal Expert Report of Joshua L. Cohen, M.D.

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

BOEHRINGER INGELHEIM	)	
PHARMACEUTICALS INC., BOEHRINGER	)	Civil Action No. 3:15-cv-5982-PGS-
INGELHEIM INTERNATIONAL GMBH,	)	TJB (consolidated with Civil Action
BOEHRINGER INGELHEIM CORPORATION,	)	Nos. 3:16-cv-00852-PGS-TJB, 3:16-cv-
and BOEHRINGER INGELHEIM PHARMA	)	00851-PGS-TJB and 3:16-cv-1727)
GMBH & CO. KG,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
HEC PHARM CO., LTD.,	)	<b>CONTAINS HIGHLY</b>
HEC PHARM USA, MYLAN	)	<b>CONFIDENTIAL</b>
PHARMACEUTICALS INC., MYLAN INC.,	)	<b>INFORMATION—SUBJECT TO</b>
MYLAN LABORATORIES LIMITED, ACCORD	)	<b>PROTECTIVE ORDER</b>
HEALTHCARE, INC., AUROBINDO PHARMA	)	
LIMITED, AUROBINDO PHARMA USA, INC.,	)	
DR. REDDY’S LABORATORIES, LTD., DR.	)	
REDDY’S LABORATORIES, INC., ZYDUS	)	
PHARMACEUTICALS USA, INC., CADILA	)	
HEALTHCARE LTD., MSN LABORATORIES	)	
PRIVATE LIMITED, MSN	)	
PHARMACEUTICALS, INC., PRINSTON	)	
PHARMACEUTICAL INC., INVAGEN	)	
PHARMACEUTICALS INC., SUN	)	
PHARMACEUTICAL INDUSTRIES LTD.,	)	
SUN PHARMA GLOBAL FZE, TEVA	)	
PHARMACEUTICALS USA, INC.,	)	
	)	
Defendants.	)	
	)	

**NON-INFRINGEMENT REPORT OF JOSHUA L. COHEN, M.D.**

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## I. INTRODUCTION

1. I, Joshua L. Cohen, M.D., having been retained by counsel for Defendants Accord Healthcare, Inc. (“Accord”), Aurobindo Pharma Limited (“Aurobindo”), Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc. (together “DRL”), HEC Pharm Co., Ltd., HEC Pharm USA Inc. (together “HEC”), InvaGen Pharmaceuticals, Inc. (“Invagen”), MSN Laboratories Private Limited, MSN Pharmaceuticals, Inc. (together “MSN”), Mylan Inc., Mylan Pharmaceuticals Inc., Mylan Laboratories Limited (together “Mylan”), Princeton Pharmaceutical Inc. (“Princeton”), Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE (together “Sun”), Teva Pharmaceuticals USA, Inc. (“Teva”), Cadila Healthcare Limited, and Zydus Pharmaceuticals (USA) Inc. (together “Zydus”) (collectively “Defendants”) in connection with the above-captioned action, hereby submit this Rebuttal Expert Report.

2. In accordance with Federal Rule of Civil Procedure 26(a)(2), this Report discloses my opinions regarding Defendants’ alleged infringement of claims 7, 9, 15, 17, 19, 25, and 26 of U.S. Patent No. 8,673,927 (the “’927 patent”),<sup>1</sup> claim 1 of U.S. Patent No. 9,173,859 (the “’859 patent”) and claims 32, 34, 39, 41, and 42 of U.S. Patent No. 8,178,541 (the “’541 patent”)<sup>2</sup> (collectively the “Combination Claims”), and the bases and reasons supporting my opinions. The patents referenced above are referred to as the “Asserted Patents.” This Report sets forth the opinions I have formed based on information available as of the date of this Report. In the event Boehringer Ingelheim, Pharmaceuticals Inc., Boehringer Ingelheim International GbmH, Boehringer Ingelheim Corporation, and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, “Boehringer” or “Plaintiffs”) submit any expert report or other response to the

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<sup>1</sup> I understand that these claims of the ’927 Patent are asserted against all Defendants except Aurobindo and DRL.

<sup>2</sup> I understand that the claims of the ’541 Patent are only asserted against HEC and Zydus.

subject matter addressed in this Report, I reserve the right to respond to such submission. This report also responds to the opinions expressed in the Expert Reports of Dr. James Lenhard and Dr. William Jorgensen, served on behalf of the Plaintiffs. I expect to be called to testify at trial in the above-captioned action.

## **II. EXPERIENCE, QUALIFICATIONS, AND PRIOR TESTIMONY**

3. I am a Professor of Medicine and Interim Director of the Division of Endocrinology and Metabolism in the Department of Medicine of the George Washington University School of Medicine and Health Sciences. I am also Interim Director of Endocrinology and an Attending Physician at the George Washington University Hospital and the George Washington University Medical Faculty Associates, where I consult and see patients referred (and self-referred) to me with endocrine disorders including diabetes.

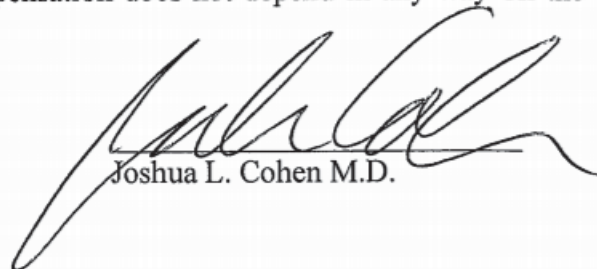
4. I received my S.B. in Chemistry from the Massachusetts Institute of Technology in 1970. I received my M.S. degree from New York University in 1975. I received my Doctorate of Medicine from New York University School of Medicine in 1978. I completed my residency at the University of Michigan Medical Center in 1981 in the Department of Internal Medicine. I then completed a research fellowship at the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases within the National Institutes of Health in 1983. I completed my fellowship training in Endocrinology and Metabolism at Johns Hopkins Hospital in the Division of Endocrinology and Metabolism in 1985. I am a Diplomate of the American Board of Internal Medicine since 1981 with subspecialty certification in Endocrinology and Metabolism since 1985. I am a Fellow of the American College of Physicians.

5. I have been a faculty member of the George Washington University School of Medicine and Health Sciences since 1985 and have been Professor of Medicine since 2010. Since joining the faculty, I have taught basic endocrine science and clinical endocrinology to medical

### **XVIII. COMPENSATION**

142. I am being compensated for my time in connection with this matter at my standard consulting rate, which is \$500 per hour. My compensation does not depend in any way on the outcome of this litigation.

Date: 10/25/17



Joshua L. Cohen M.D.